A Study to Assess The Correlation Between Cardiac Magnetic Resonance Imaging (CMR), Echocardiography and, When Available, Right Heart Catheterisation in The Evaluation of Pulmonary Arterial Pressure

A Dissertation Submitted in Partial Fulfilment of

M.D Radiodiagnosis (Branch VIII) Examination of

THE TAMIL NADU Dr M.G.R MEDICAL UNIVERSITY, CHENNAI

To be held in April, 2016

C E RT I F I C A T E

This is to certify that the dissertation entitled "A Study to Assess The Correlation Between Cardiac Magnetic Resonance Imaging (CMR), Echocardiography and, When Available, Right Heart Catheterisation in The Evaluation of Pulmonary Arterial Pressure" is the bonafide original work of Dr. Paul Deepak S. submitted in partial fulfilment of the requirement for M.D Radio Diagnosis (Branch- VIII) Degree Examination of The Tamil Nadu Dr M.G.R Medical University, Chennai to be conducted in April, 2016.

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DECLARATION

I, Dr. Paul Deepak S., hereby declare that this dissertation entitled "A Study to Assess The Correlation Between Cardiac Magnetic Resonance Imaging (CMR), Echocardiography and, When Available, Right Heart Catheterisation in The Evaluation of Pulmonary Arterial Pressure" is an original work done by me in partial fulfilment of the requirement for M.D Radio Diagnosis (Branch- VIII) Degree Examination of The Tamil Nadu Dr M.G.R Medical University, Chennai to be conducted in April, 2015.

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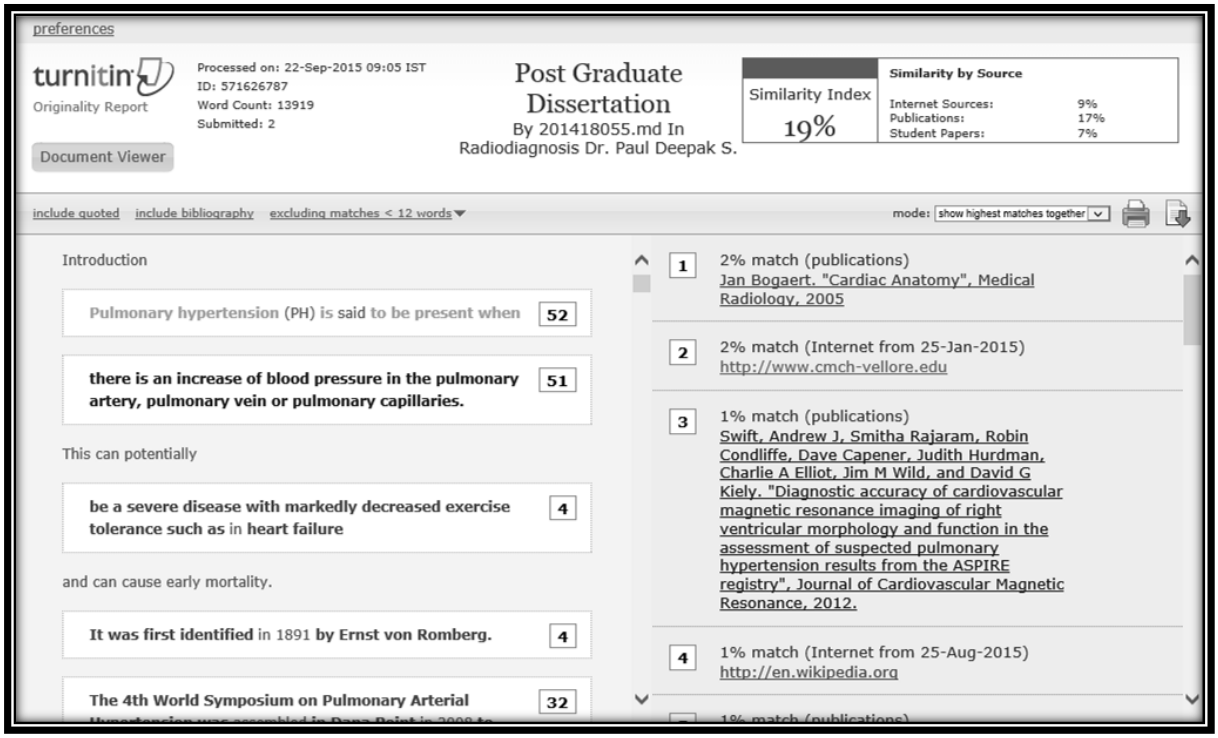

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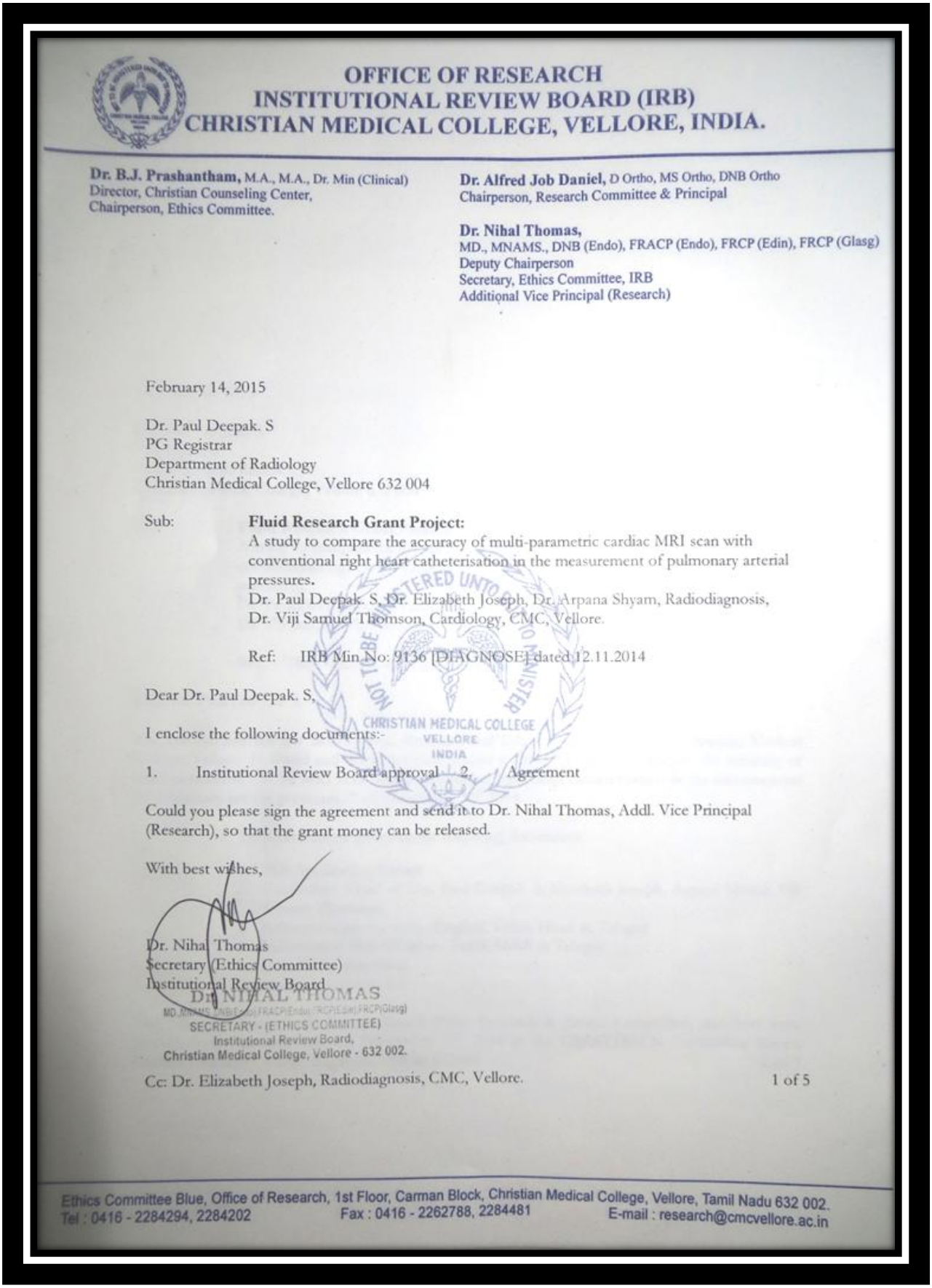

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Sub: **Fluid Research Grant Project:**
A study to compare the accuracy of multi-parametric cardiac MRI scan with conventional right heart catheterisation in the measurement of pulmonary arterial pressures.
Dr. Paul Deepak. S, Dr. Elizabeth Joseph, Dr. Arpana Shyam, Radiodiagnosis,
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I enclose the following documents:-

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Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events,** occurring in the course of the project, **annual report,** any **amendments in the**

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Table of Contents

Introduction

Pulmonary hypertension (PH) is said to be present when there is an increase of blood pressure in the pulmonary artery, pulmonary vein or pulmonary capillaries. This can potentially be a severe disease with markedly decreased exercise tolerance such as in heart failure and can cause early mortality.

It was first identified in 1891 by Ernst von Romberg.

The 4th World Symposium on Pulmonary Arterial Hypertension was assembled in Dana Point in 2008 to modify the previous classification based on new understandings of disease mechanisms. The Updated Clinical Classification system can be summarised as follows (1):

- WHO Group I - Pulmonary arterial hypertension (PAH)
- WHO Group I' - Pulmonary veno-occlusive disease (PVOD) and/ or pulmonary capillary haemangiomatosis (PCH)
- WHO Group II - Pulmonary hypertension owing to left heart disease
- WHO Group III - Pulmonary hypertension owing to lung disease and/or hypoxia
- WHO Group IV - Chronic thrombo-embolic pulmonary hypertension (CTEPH)
- WHO Group V - Pulmonary hypertension with unclear multi-factorial mechanisms

During the 5th World Symposium held in Nice, France, in 2013, the consensus was reached to maintain the general scheme of previous clinical classifications. (2).

Because pulmonary hypertension can be any one of five major types, a series of investigations must be performed to distinguish pulmonary arterial hypertension from venous, hypoxic, thrombo-embolic, or miscellaneous varieties. These would generally include pulmonary function tests; blood tests; electrocardiography (ECG); Plain radiographs of the chest (and High Resolution CT scan if interstitial lung disease is suspected); and ventilation-perfusion (V/Q) scan to exclude chronic thrombo-embolic pulmonary hypertension.

Normal pulmonary arterial pressure when a person is living at sea level has a mean value of 8–20 mm Hg (1066–2666 Pa) at rest. Pulmonary hypertension is said to be present when mean pulmonary artery pressure exceeds 25 mm Hg (3300 Pa) at rest. A systolic pressure of 40 mm Hg most often implies a mean pressure greater than 25 mm Hg. Roughly, mPAP = 0.61*sPAP + 2 (3).

Pulmonary artery catheterisation

Pulmonary arterial pressure can be calculated indirectly with Echocardiography. PAOP (pulmonary artery occlusion pressure) and PVR (pulmonary vascular resistance) cannot be measured directly with Echocardiography. Invasive measurement of pulmonary artery pressures using a Swan-Ganz catheter is considered the gold standard. Diagnosis of PAH, therefore requires right-sided cardiac catheterisation. Measurement of pulmonary arterial pressures along with cardiac output is far more important in measuring disease severity than pulmonary arterial pressure measurements alone.

Rationale for the study:

Right Heart Catheterisation is an invasive technique that requires the use of ionizing radiation and has considerable procedure related risks. Hence Pulmonary Hypertension is most often diagnosed on echocardiography as it is inexpensive, portable, widely available, does not involve ionizing radiation and is non-invasive. However, mean Pulmonary Artery Pressure (mPAP) as derived on echocardiography is inaccurate and operator dependant. Moreover the prognosis of Pulmonary Hypertension depends on various measurements involving the right ventricle, which are sub-optimally imaged on Echocardiography owing to its retro-sternal location and complex anatomy. Cardiac MRI is excellent for imaging the right ventricle, and allows accurate measurements owing to its multi-planar capabilities. It is also a validated tool for measuring velocities and flow measurements. From the above measurements, it is possible to calculate pulmonary arterial pressures that will help in the diagnosis and severity assessment of pulmonary hypertension. Hence, cardiac MRI is a versatile and ideal tool for the evaluation of pulmonary hypertension and is widely used for this purpose in developed countries.

To the best of our knowledge, no study has been published in India on the role of MRI in pulmonary hypertension. Also, though several studies have already shown significant relationship between cardiovascular magnetic resonance (CMR) derived measurements with mPAP and PVR in patients with pulmonary hypertension, very few retrospective studies and no prospective studies have compared the actual direct measurement of right heart pressures with MRI derived values. Therefore this study would be one of few of its kind in India.

Aims and objectives

Aim of the study

To study the correlation between Cardiac Magnetic Resonance Imaging (CMR), Echocardiography and, when available, right heart catheterisation in the evaluation of pulmonary arterial pressure.

Primary objectives:

1. To assess the accuracy of CMR when compared to Echocardiography and right heart catheterisation (when available), using quantitative parameters, in the measurement of pulmonary arterial pressures in patients with clinically suspected HT or when suspected on cardiac MRI.

2. To evaluate the correlation between various parameters in CMR to pulmonary arterial pressures measured on Echocardiography and right heart catheterisation (when available) using quantitative parameters.

Secondary objective:

1. To describe and characterise the various CMR imaging features seen in the subset of our subjects with pulmonary hypertension diagnosed on Echocardiography qualitatively.

Literature review

Pulmonary Hypertension (PH) is a complex group of disease entities with various aetiologies that have a common measurable abnormality that is elevated pulmonary arterial pressure. Pulmonary hypertension is said to exist when mean pulmonary artery pressure (mPAP) is greater than or equal to 25 mmHg measured at cardiac catheterisation (4). However, right heart catheterisation is rarely performed solely for the diagnosis of pulmonary hypertension. This is owing to the fact that right heart catheterisation is an invasive procedure with significant risk to the patient and involves the use of X-rays exposing the patient to harmful radiation.

Causes of pulmonary hypertension are galore and may be secondary to disease affecting the heart, lungs and liver. Strictly speaking, the term pulmonary arterial hypertension (PAH) must only be applied to a rare, progressive condition characterised by a vasculopathy, although it is often used interchangeably with pulmonary hypertension. Mild elevations of pulmonary artery pressure are commonly seen in association with several respiratory conditions such as asthma, chronic obstructive airway disease and interstitial lung diseases. It is also seen in several cardiac diseases such as congenital heart diseases, rheumatic heart disease and even in ischaemic heart disease. The 4th world symposium on pulmonary arterial hypertension met at Dana Point is 2008 and modified the aetiological classification of Pulmonary Hypertension, the main categories of which are stated in the introduction. (1). During the 5th World Symposium held in Nice, France, in 2013, the consensus was reached to maintain the general scheme of previous clinical classifications. The modified classification is as follows:

Updated Classification of Pulmonary Hypertension (2)

1. Pulmonary arterial hypertension 1′ Pulmonary veno-occlusive disease and/or pulmonary capillary hemangiomatosis **1″. Persistent pulmonary hypertension of the newborn (PPHN)**
2. Pulmonary hypertension due to left heart disease
3. Pulmonary hypertension due to lung diseases and/or hypoxia
4. Chronic thromboembolic pulmonary hypertension (CTEPH)
5. Pulmonary hypertension with unclear multifactorial mechanisms

Whatever be the underlying cause, the ultimate outcome of patients who develop high pressures in their pulmonary arteries is the same. An increase in mPAP and pulmonary vascular resistance (PVR) results in right ventricular failure. The initial symptoms include dyspnoea and decreased tolerance to exertion. Eventually death results, with a median survival after diagnosis in untreated patients of less than 3 years (5,6).

Right Heart Catheterisation

Right heart catheterisation (RHC) is the gold standard investigation to determine the presence or absence of PH by directly measuring mean pulmonary artery pressure (mPAP). In addition, Right Heart Catheterisation also allows measurement of cardiac

output (CO) and index (CI, which is the cardiac output in litres per minute per unit body surface area), right atrial pressure, mixed venous oxygen saturation and PVR, which are used as markers of disease severity. However, although safe in expert hands it is an invasive test requiring the patient to have a femoral or jugular puncture and intra-vascular catheterisation for accessing the heart chambers and most often requires at least one day of hospital stay. Moreover, ionising radiation (X-rays) are used for guiding the catheter. (7)The expertise and infra-structure required for performing right heart catheterisation are not widely available and even in advanced centres where these may be available; it is seldom performed for the diagnosis of Pulmonary Hypertension alone. It also adds cost to the patient and the health system. Therefore the role of Right heart catheterisation is limited in confirming a diagnosis of PH and is often used only in selected cases for assessing the response to treatment.

Echocardiography

Echocardiography is currently the most commonly used non-invasive test in patients with suspected Pulmonary Hypertension. It has definite advantages of being inexpensive, widely available and does not involve ionising radiation. It is also fairly easy to perform requiring no great equipment or expertise. Mean pulmonary arterial pressure (mPAP) on Echocardiogram is calculated as follows:

The peak velocity of the regurgitant jet at tricuspid valve is first determined. This is represented as TV V2max and is representative of the difference in pressures between the right atrium and the right ventricle. From this value, the maximum

pressure gradient across the tricuspid valve is calculated by squaring this value and multiplying it by four.

- $[TV\ V2\ max]^2$ x4 = TV max PG

Where TV V2 max stands for maximum velocity of the regurgitant jet at the tricuspid valve, TV max PG stands for the maximum pressure gradient across the tricuspid valve.

To this, an arbitrary right atrial pressure of 5 to 7mmHg is added to yield the Pulmonary Artery Systolic Pressure (PASP). The latest is to use RA pressure estimates from the distensibility and collapsibility of the IVC. From this, the mean Pulmonary Artery Pressure may be deduced as follows:

- mPAP = o.61 x PASP + 2mmHg (3)

Where mPAP stands for mean pulmonary artery pressure as derived on Echocardiogram and PASP stands for pulmonary artery systolic pressure derived on Echocardiogram.

However, Echocardiogram has a number of limitations in the assessment of pulmonary pressures and does not perform well for certain aetiologies of PH (8,9). Firstly, it is subjective and observer dependant with considerable inter-observer variability in measurements. Secondly, the pressures are not directly measured, but inferred from other velocity measurements. Thirdly, the right ventricle has a unique position behind the sternum and hence is difficult to access and fully assess using ultrasound and Doppler signals. Consequently, Echocardiogram significantly over and

underestimates invasively measured mPAP(10). Owing to this intrinsic difficulty with the pressure measurements, Echocardiography relies on a number of indirect indicators of right heart function for corroboration. This includes right ventricular volumes such as end diastolic volume and ejection fraction. This s however inaccurate because Echocardiogram uses the standard ellipsoid formula for volume calculation wheras the shape of the right ventricle is not like and ellipsoid but more like a teapot, with the tricuspid valve forming the mouth and the right ventricular outflow tract forming the spout. Other indirect indicators such as contraction of the right ventricle as quantified by tricuspid annular plane systolic excursion (TAPSE) and septal bounce, or bowing of the inter-ventricular septum to the left during systole, though useful, are late features in pulmonary hypertension. Consequently, there is increasing interest in developing other imaging tools that combine the accuracy of right heart catheterisation and the non-invasive ease of Echocardiogram.

ESSENTIALS OF MRI AND SPECIFIC FEATURES OF CARDIAC MRI (11)

The nuclear spin phenomenon, T1 and T2 relaxation

Hydrogen protons in our body associated with fat and water molecules are positively charged and spins about its axis acting like tiny magnets, they are randomly aligned such that their magnetic fields cancel each other out rather than sum up. In MRI examination, the patient is made to lie in a high strength static magnetic field. The external magnetic field aligns the spins of the human body, some along the direction of the external magnetic field and some in the opposite direction. The interaction with the external magnetic field also results in precession of the protons. The Larmor equation determines the precessional frequency as f = gyromagnetic ratio x main magnetic field. The gyromagnetic ratio is constant and is characteristic for each type of nuclei.

The number of spins aligned in the direction of the external magnetic field being in excess produces a net magnetization (protons aligned in the direction of the external magnetic field minus protons aligned in the direction opposite to the external magnetic field). The net magnetization is the resting state, the most favorable situation energetically.

Resonance is a property that allows efficient transfer of energy. The net magnetization is in a direction parallel to the external magnetic field which is to say it is in the longitudinal direction (z direction). A radiofrequency pulse of certain amount

of energy is transferred to the protons via the principle of resonance (excitation) such that the net magnetization flips to a certain degree rotating away from the longitudinal direction. The extent of rotation depends on the strength and duration of the RF pulse. The RF pulse strength and duration can be controlled. A 90 degree RF pulse rotates the net magnetization into the transverse plane (xy plane, x direction being left- right direction, y direction being anterior- posterior direction). A 180 degree RF pulse rotates the net magnetization into the - z direction.

After excitation, the spins of the protons return to their resting state. The magnetic component along the magnetic field increases and the component along the transverse plane or - z direction decreases. T1 relaxation is the gradual recovery of the magnetic field component along the net magnetization. T2 relaxation is the gradual disappearance of magnetization in the transverse plane (11).

Slice encoding, Phase encoding, frequency encoding

T1 and T2 relaxation in itself is not enough to construct an image. Spatial encoding is a phenomenon whereby magnetic field gradients are applied over a volume of interest and an image is constructed. The process is based on the Larmor equation. The MR signal is localized by applying gradients that produce controlled linear variations in the magnetic field. These gradients are used in slice selection (z), phase encoding (y) and frequency encoding (x).

Slice selection gradient determines the amount of tissue that is excited by the RF pulse. Phase encoding gradient is applied perpendicular to the slice selection gradient and after the initial excitation. Frequency encoding is also referred to as the readout gradient since MR signal is acquired during the frequency encoding. It is applied to the third perpendicular direction to slice the selection and phase the encoding gradients. The protons are encoded with different frequency depending on their locations.

k-space

The data obtained from the gradients are stored in a matrix referred to as the k-space. High signal information is represented in the center and low signal information near the periphery, in the edges. Fourier transformation is then used on this information in the k-space to reconstruct images.(12)

Spin Echoes and Gradient Echoes

Spin Echo pulse sequences are now abandoned due to excessive motion artifacts. Fast spin Echo / Turbo spin Echo techniques are now employed which can acquire image in a single breath hold. They are made of a number of excitation pulses separated by a given time interval (TR). A period called the time of Echo (TE) is the time between start of an RF pulse and the maximum in signal. It is repeated every TR (time of repetition) seconds. The TR is adjusted to coincide with one single R-R interval of the patient's ECG.

Steady State Free Precision

Synchronization with ECG during cardiac MRI is extremely important. SSFP sequence is a modification of gradient Echo imaging wherein bright blood images are produced that contrasts the background myocardium resulting in a clear delineation between them. It is acquired by obtaining a steady state magnetization maintained between successive cycles. The high temporal resolution, excellent contrast between myocardium and blood within the chambers, and favorable SNR (signal to noise ratio) make it good for evaluation of wall motion and volumetric measurement.

Figure 1

TRUFISP axial section through the thorax at the level of the main pulmonary artery bifurcation.

The ascending and descending aorta are discerned.

Both the lungs are visualized and appear unremarkable.

Advantages of cardiac MRI

1. Non invasive investigation with no ionizing radiation being involved.

2. Three dimensional modality making it ideal for assessing structures in any plane, especially cardiac chambers.

3. Now considered the gold standard for volumetric measurements of the right heart.

4. Pulmonary vasculature, lungs and systemic arteries of the chest are visualized in the study thereby providing a way to exclude other causes of pulmonary hypertension such as pulmonary embolism left sided causes such as mitral valve stenosis or various lung conditions such as interstitial lung disease.

5. The 4D function of cardiac MRI gives accurate information of cardiac muscle mass and ventricular volumes and is not limited in visualisation nor is it operator dependant as Echocardiography.

6. Velocity encoded imaging across any plan making flow related measurements available from the pulmonary artery.

Disadvantages of cardiac MRI

1. Relatively a lengthy examination, taking 30 to 60 minutes of machine time for a detailed evaluation.

2. Patients suffering from claustrophobia, arrhythmias, obesity and those who are short of breath and have difficulty lying down may not be able to tolerate the examination.

3. Registration artifacts occur in the images resulting in blurred images in patients with tachycardia and irregular cardiac rhythm.

4. The technology is not yet widely available and only few physicians are trained to perform and interpret these examinations.

5. Much clinical research is still needed to optimize the diagnostic algorithms in cardiac disease. Much awareness amongst cardiologist and adequate scientific literature with outcome analysis is required for fully comprehending the true value in diagnostic testing in specific clinical scenarios.

MRI ANATOMY OF THE HEART

Steady state free precession sequences are best to depict the cardiac anatomy. The heart is an intra thoracic organ which rests on the anterior aspect of the diaphragm in an oblique position with the lungs on both sides, and its apex in the left hemithorax.

Cardiac structures:

Right atrium (13):

The right atrium is seen as the right heart border on the frontal chest radiograph. Embryologically it develops from the sinus venous and the primitive auricle.

Characteristic features that distinguish the right atrium are:

1) The venous component receiving the IVC and SVC in the posterior aspect and the coronary sinus in the inferior aspect

2) The broad based, triangular shaped appendage

3) A ridge called the crista terminalis which separates the venous part and the appendage

4) Limbus of the fossa ovalis on the septal aspect.

Enlargement of the right atrium displaces the adjacent lung and enlargement of the appendage obliterates the retrosternal clear space.

Left atrium:

This forms the upper posterior heart border lying just inferior to the carina and anterior in relation to the esophagus. Also forms from the sinus venosus and primitive auricle embryologically.

Characteristic features that distinguish the left atrium are

1) The venous component receiving the four pulmonary veins at the corner of its posterior surface

2) Long finger like left atrial appendage that overlies the left atrioventricular groove and left circumflex coronary artery

3) Absence of features that suggest right atrial morphology.

When the left atrium is enlarged, it displaces the esophagus towards the posterior aspect. It also causes widening of the carina angle. Massive enlargement results in the left atrium forming the right heart border on the frontal chest radiograph. Enlargement of the appendage displaces the adjacent lung.

Atrial septum:

The inter-atrial septum separates the left atrium from the right. It is best seen in the horizontal / transverse views and longitudinal / four chamber views. It is seen as a thin line separating the two atria except at the level of the foramen ovale which is very thin and therefore technically difficult to demonstrate, resulting in misinterpretation as an atrial septal defect which should be avoided.

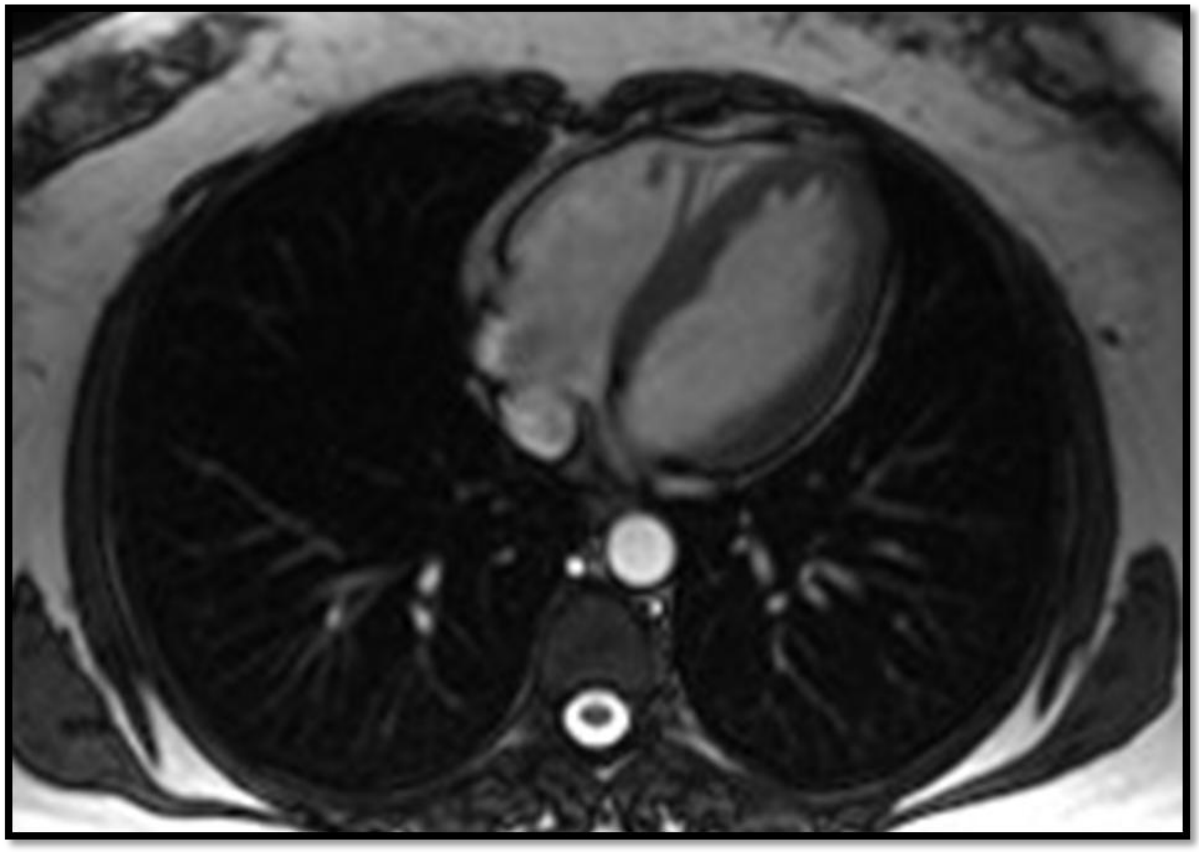


Figure 2.

TRUFISP axial image of the thorax at the level of the ventricles showing normal anatomy.

The left ventricular free wall and the interventricular septum are apparent.

The right ventricular free wall is almost indiscernible, which is normal. The moderator band is distinctly seen.

The pericardium is distinctly made out as a thin hypo-intense line surrounded by bright signal from the hyper-intense mediastinal and epicardial fat on both sides.

Visualized lung fields are unremarkable.

Right ventricle (13):

Pyramidal shaped chamber which rests on the diaphragm and forms the inferior and anterior heart border. The right ventricle does not from any part of the apex of the heart.

Characteristic features that distinguish the right ventricles are

1) Tendinous chord attachment of the tricuspid valve leaflets to the ventricular septum

2) The moderator band (muscular band) containing a continuation of the right bundle branch and passing from the ventricular septum to the anterior wall

3) The tricuspid valve and the pulmonary valves are separated by crista supraventricularis which is an in-folding of the roof of the ventricle in the posterior margin of the infundibulum.

When compared to the left ventricle, the right ventricular wall is thin and measures 3-4 mm at end diastole. Further thinning of the free wall towards the RV apex is normal.

Enlargement of the RV chamber results in obliteration of the retrosternal clear space and because this space is a small space, the resultant effect of further enlargement is that there is displacement of the left ventricle leftward and posteriorly, and the apex backward and superiorly.

Left ventricle:

Cone shaped thick walled chamber with its long axis in the left anterior and inferior direction. It forms the inferior part of the left heart border, part of the posterior heart border and the apex. Its base is formed by the fibrous skeleton of the inlet and outlet valves and its apex is the apex of the heart.

Characteristic features that distinguish the left ventricle are

1) Fibrous continuity of the inlet and outlet valves due to absence of conus or infundibulum

2) Two papillary muscles – the anterolateral and the posteromedial papillary muscles that arise from only the free wall of the ventricle

3) Absence of features characteristic for right ventricle.

The myocardial thickness in the left ventricle measured in the lateral wall at end diastole is 7-8 mm in women and 8-9 mm in men. The apex is thinner and measures about 3 mm. Wall thickness is not uniform; it is most pronounced in the longitudinal direction with gradual thinning toward the apex and less so in the circumferential direction.

Ventricular septum:

The interventricular septum is a thick walled muscular layer that separates the right ventricle from the left ventricle. At the sub-aortic location the muscular layer is thin and is called the membranous septum.

The interventricular septum is convex shaped towards the right ventricle which is maintained throughout the cardiac cycle.

Valves:

The mitral valve is always connected to the morphological left ventricle and the tricuspid valve to the morphological right ventricle.

The tricuspid valve is more apically positioned in comparison to the mitral valve; this allows differentiation of the ventricular morphology. The tricuspid valve has 3 leaflets, septal, inferior and antero-superior leaflets. (12)

The mitral valve has 2 leaflets, aortic and mural leaflets.

The semilunar valves attach at the anatomic ventriculo-atrial junction. Both have three cusps.

The valve leaflets are thin and fibrous therefore the leaflet morphology, motion and abnormal opening and valvular flow patterns may not be optimally assessed.

Pericardium:

The pericardium covers the heart along with the origin of the great vessels. It consists of the fibrous part and the serous part. The fibrous part is attached to the sternum and the diaphragm. The serous part consists of the visceral layer that is in contact with the heart and the pericardial fat and the parietal part which is in contact with the inner surface of the fibrous pericardium. The visceral layer reflects at the heart and the root of the great vessels onto the inner surface of the fibrous part of the pericardium thus becoming continuous with it.

The pericardial cavity lies between the two layers of the serous part of the pericardium and contains about 20-25 ml of serous fluid. This may vary in individuals. Two serosal tunnels are present- the transverse sinus, posterior in location to the great arteries and anterior to the atria and superior vena cava with its four recesses, the superior aortic recess, inferior aortic recess, left pulmonic recess, right pulmonic recess, and the oblique sinus, posterior in location to the left atrium.

On magnetic resonance, the normal pericardium is seen as an extremely thin hypo-intense curvilinear structure with hyper=intense mediastinal and epicardial fat on both sides. It measures 1.2+/- 0.5 mm in diastole and 1.7+/-0.5 mm in systole. Thickening of the pericardium the measures more than 4 mm is significant.(14)

Planes for MR imaging of the heart

Scout images: Scout image is taken in the axial plane. Axial images display normal anatomy and relationship of the great vessels and cardiac chambers and the pericardium depicting the morphology in a plane that is familiar to general radiologist. However quantitative measurement of wall thickness, cavity dimensions and functional data cannot be assessed. Images can also be taken in any desired orthogonal views.

The heart lies oblique in the thoracic cavity. The true long axis of the heart is oriented 45 degrees to the mid-sagittal plane of the thoracic spine. To obtain correct inclinations for imaging along the cardiac axes, the following is done:

- ***Vertical long axis plane:*** on an axial scout, a plane is chosen that runs through the apex of the left ventricle and the middle of the left atrio-ventricular valve which is the mitral valve.

- ***Horizontal long axis / four chamber view:*** on the vertical long axis, a plane is chosen that runs through the apex and the middle of the mitral ring.

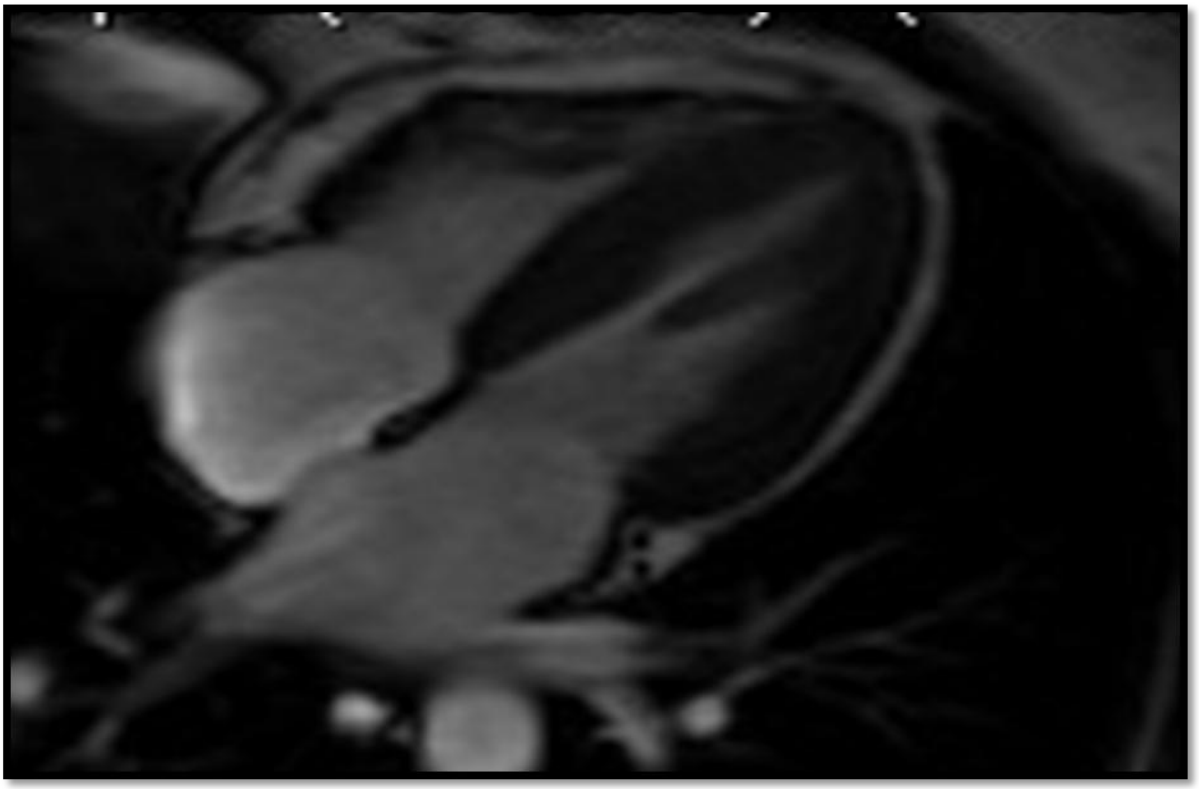


Figure 3. Four chamber view in systole.

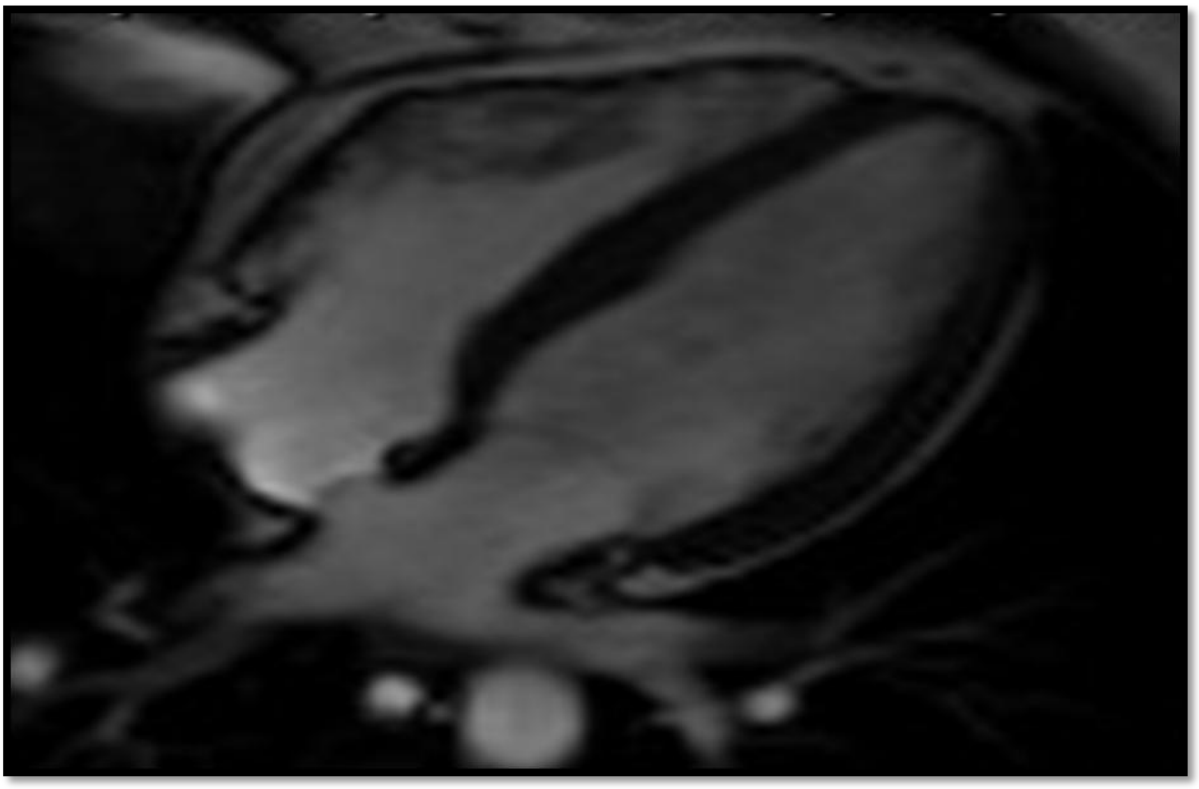


Figure 4. four chamber view in diastole.

- ***Short axis plane:*** the short axis plane is taken as that which is perpendicular to the horizontal long axis and vertical long axis plane.

- ***True 4 chamber view:*** in a short axis view, a plane is taken that passes from the superior most mitral valve, antero-lateral papillary muscle to the inferior angle of the right ventricle anteriorly and through the midpoint of the interventricular septum, to get the true 4 chamber view.

- ***True short axis plane:*** is taken perpendicular to the true 4 chamber view. No single plane is absolutely perpendicular to both the ventricular walls however the plane that is positioned parallel to the mitral valve between the anterior and posterior atrio-ventricular groove is best.

- From the true short axis plane, the vertical long axis, horizontal long axis, the left ventricular inflow / outflow can be acquired.

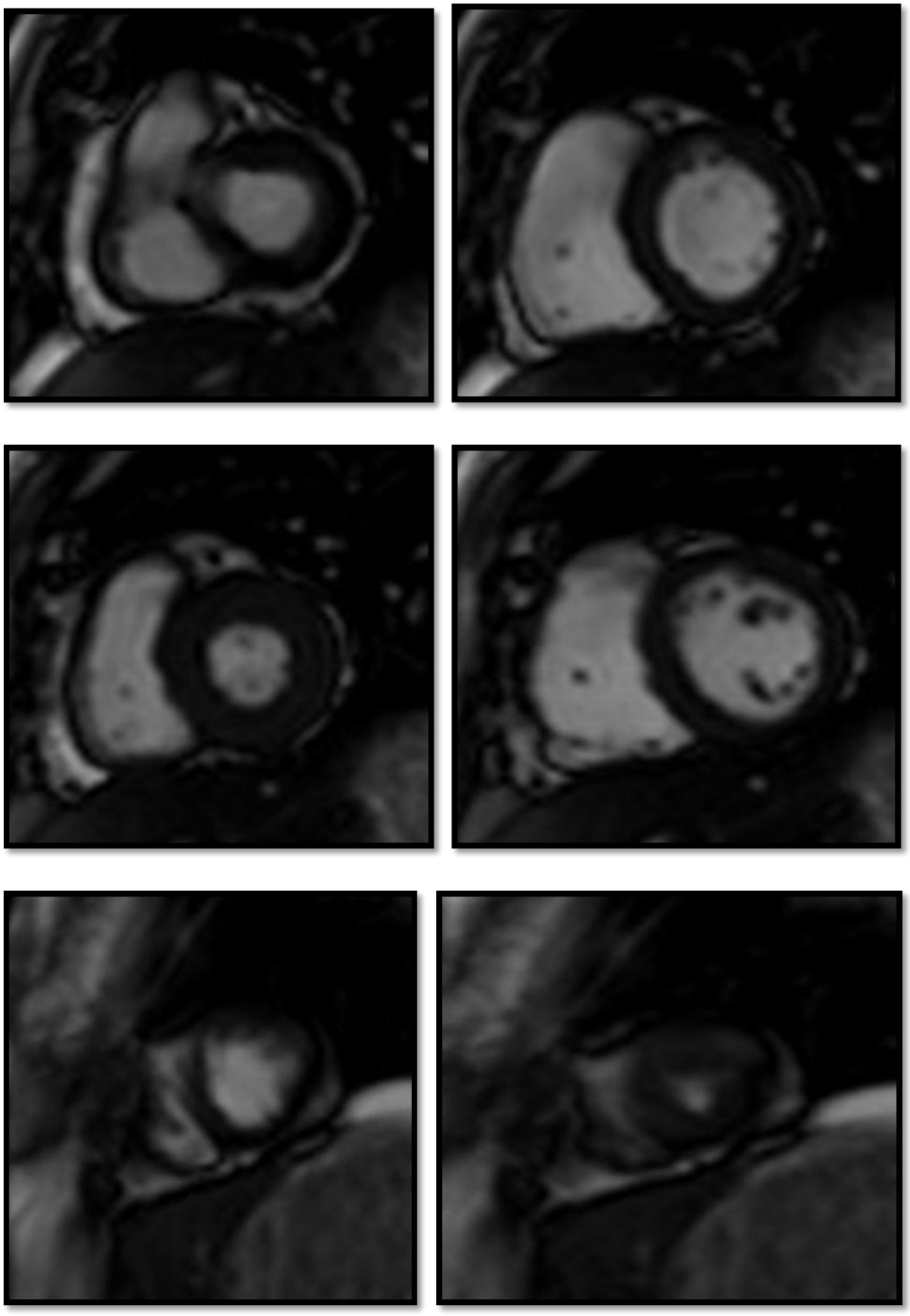


Figure 5. MRI CINE short axis at systole and diastole at basal, mid-cavity and apical levels

Cardiac function:

Cine MRI is used to visualize cardiac motion. It is similar to Echocardiography. The main advantage of cine MRI in the myocardial wall motion evaluation and LV function when compared to Echocardiography is its ability to sharply delineate endocardial borders. This superior quality of cardiac MRI allows us to interpret and quantify more accurately and consistently the LV function. Of course the question of poor acoustic window does not arise with cardiac MRI. In one particular study that assessed quality of the images taken in 208 patients as part of its analysis, showed that only 51% of the Echocardiograms were considered to be of good or very good image quality, whereas 82% of the MR equivalents were graded highly(15).

Modified Simpson rule- volume of an object can be estimated by taking the sum of the cross sectional areas of each section and multiplying by the section thickness. (16)

A stack of short axis cine images is taken and the volume is assessed at end systole and end diastole. Ejection fraction is calculated as the difference of LV volumes at end systole and end diastole divided by the left ventricular volume at end diastole. Papillary muscles are included in the blood pool by consensus. The stacks of short axis images are acquired in the steady state free precision sequence which results in an excellent contrast between the blood pool and the myocardium. This contrast is maintained however ischemic or distorted by disease the chamber is. Therefore there

is no requirement for geometric assumption at any point in time, making the assessment of ejection fraction very accurate and the inter study variation very less.

Cardiac Magnetic Resonance Imaging in Pulmonary Hypertension

Cardiac Magnetic Resonance Imaging (CMR) is a versatile tool for the assessment of the right ventricle. Several studies have shown significant relationships between cardiovascular magnetic resonance (CMR) derived measurements with mean pulmonary artery pressures (mPAP) and pulmonary vascular resistance (PVR) as measured by right heart catheterisation in patients with PH(17).

Accurate volume measurements of the right ventricle are possible on CMR using ECG gated cine imaging where the heart is imaged throughout the cardiac cycle along any plane. For routine cardiac imaging, cine images are obtained along the short axis of the heart or left ventricle such that it is easy to trace the endocardium of the left ventricle for calculation of LV function.

Endocardium of the right ventricle is more easily traced on true axial images and true axial cine images are thought to be better for assessing right ventricular volume functions. However, the difference is only in the matter of ease of endocardial tracing and there is no significant change in the accuracy compared with volumes traced out on short axis cine images.

The volumetric data that may be obtained from CMR using appropriate software includes the following:

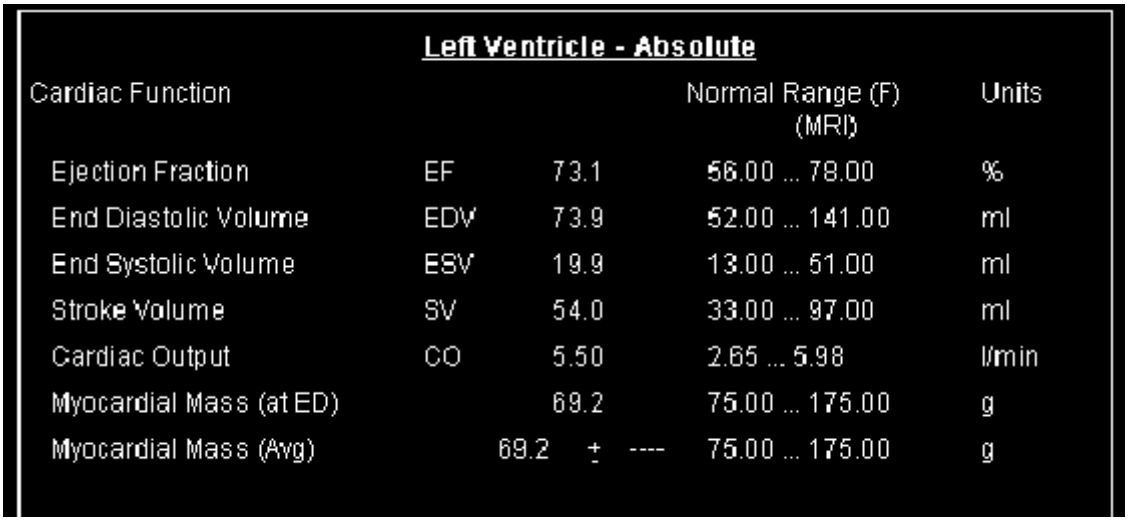
i) End Diastolic volume of the ventricle

ii) End systolic volume of the ventricle

iii) Ventricular stroke volume

iv) Ventricular ejection fraction

v) Cardiac output



Left Ventricle - Absolute

Cardiac Function				Normal Range (F) (MRI)	Units
Ejection Fraction	EF	73.1		56.00 ... 78.00	%
End Diastolic Volume	EDV	73.9		52.00 ... 141.00	ml
End Systolic Volume	ESV	19.9		13.00 ... 51.00	ml
Stroke Volume	SV	54.0		33.00 ... 97.00	ml
Cardiac Output	CO	5.50		2.65 ... 5.98	l/min
Myocardial Mass (at ED)		69.2		75.00 ... 175.00	g
Myocardial Mass (Avg)		69.2	± ----	75.00 ... 175.00	g

Figure 6.

Analysis of left ventricular endocardial and epicardial tracings on short axis cine images in the End Systolic and End diastolic phases using the SIEMENS post-processing software called ARGUS.

The ventricular mass is obtained by tracing the epicardium in diastole. The right ventricular muscle volume is obtained by calculating the volume of the area between the epicardium and the endocardium. From this right ventricular mass is obtained by multiplying the muscle volume with the specific gravity of the cardiac muscle.

All of the above values may be indexed or normalised by dividing the value by the patient's body surface area obtained from patient's height and weight. This renders the measurements more comparable between individuals of different statures.

Left Ventricle - Normalized

Cardiac Function				Normal Range (F) (MRI)	Units
End Diastolic Volume	EDV	52.4		41.00 ... 81.00	ml/m^2
End Systolic Volume	ESV	14.1		11.90 ... 20.74	ml/m^2
Stroke Volume	SV	38.3		26.00 ... 56.00	ml/m^2
Cardiac Index	CI	3.91		1.75 ... 3.80	l/min/m^2
Myocardial Mass (at ED)		49.1		63.00 ... 95.00	g/m^2
Myocardial Mass (Avg)		49.1	± ----	63.00 ... 95.00	g/m^2

Figure 7.

Indexed or normalised left ventricular volumes and mass generated by the ARGUS post-processing software for SIEMENS along with the normal ranges.

Many other indicators of right ventricular function including those used in Echocardiogram may also be calculated using CMR. These include:

- Tricuspid annular plane systolic excursion [TAPSE] calculated on four chamber cine images(18). The distance from the tricuspid annulus to the apex of the heart is measured in systole and diastole. The systolic value is subtracted from the diastolic value and represents the linear movement of the tricuspid annulus during contraction. This indicates the longitudinal contraction of the right ventricle.

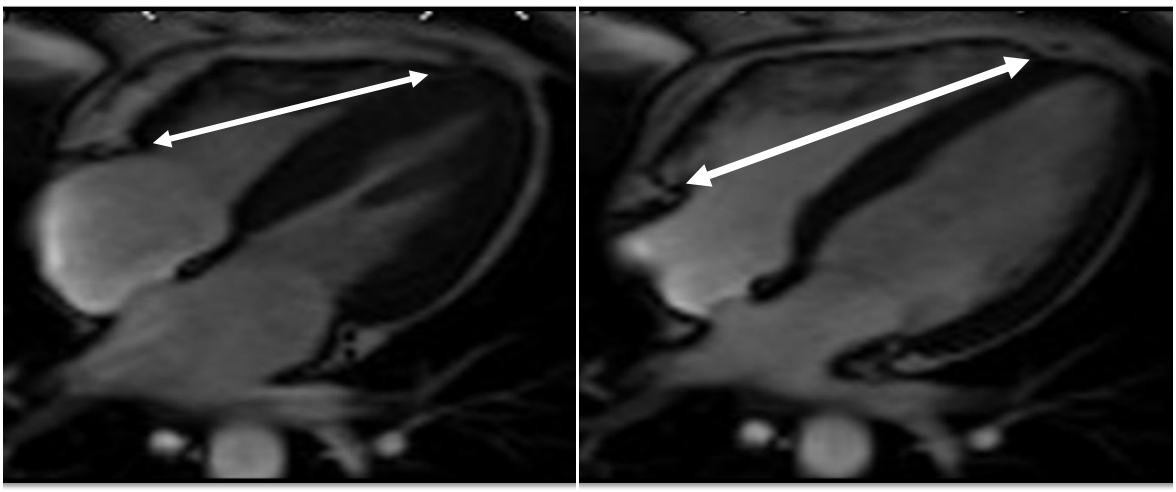


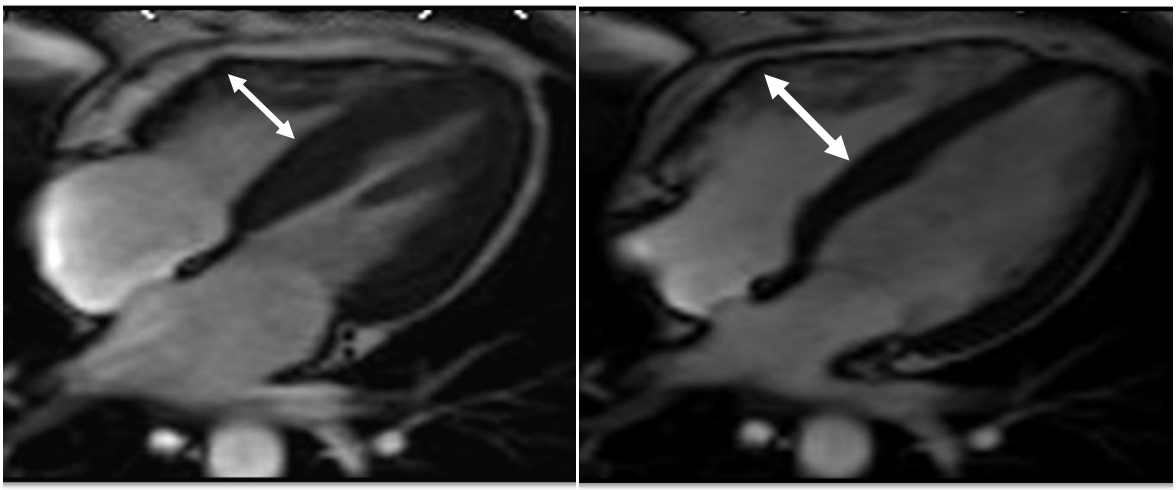
Figure 8. [a] and [b]

Four chamber views in [a] – systole and [b] – diastole.

TAPSE is obtained by subtracting the length of the line in [a] from that in [b]

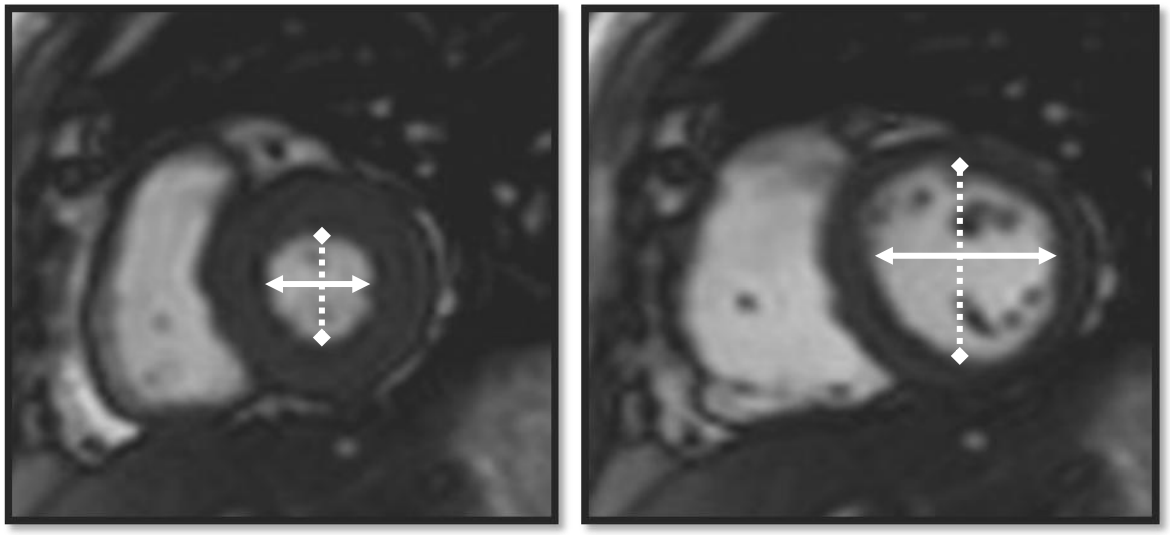
- Fractional tricuspid annulus-apex distance change [f-TAAD]. This is calculated from the above value where the TAPSE is divided by the distance between the tricuspid annulus and apex in systole and multiplied by 100 to give a percentage value of the same.

- Septum-free-wall perpendicular distance [SFD & fractional SFD]. This is also calculated on four-chamber CINE images to assess the transverse function of the right ventricle. The perpendicular distance from the septum midpoint between the apex and base are calculated as the septum-free-wall distance [SFD]. Values are obtained in systole and diastole and the difference is obtained. Fractional SFD may be calculated by dividing this value by the septum to free wall distance in diastole expressed as a percentage. In a study by Kind T, et al, right ventricular ejection fraction was thought to be better reflected by transverse rather than longitudinal wall motion in the presence of pulmonary hypertension (19).



- Figure 9. [a] and [b]
- Four chamber views in [a] – systole and [b] – diastole.
- SFD is obtained by subtracting the length of the line in [a] from that in [b]

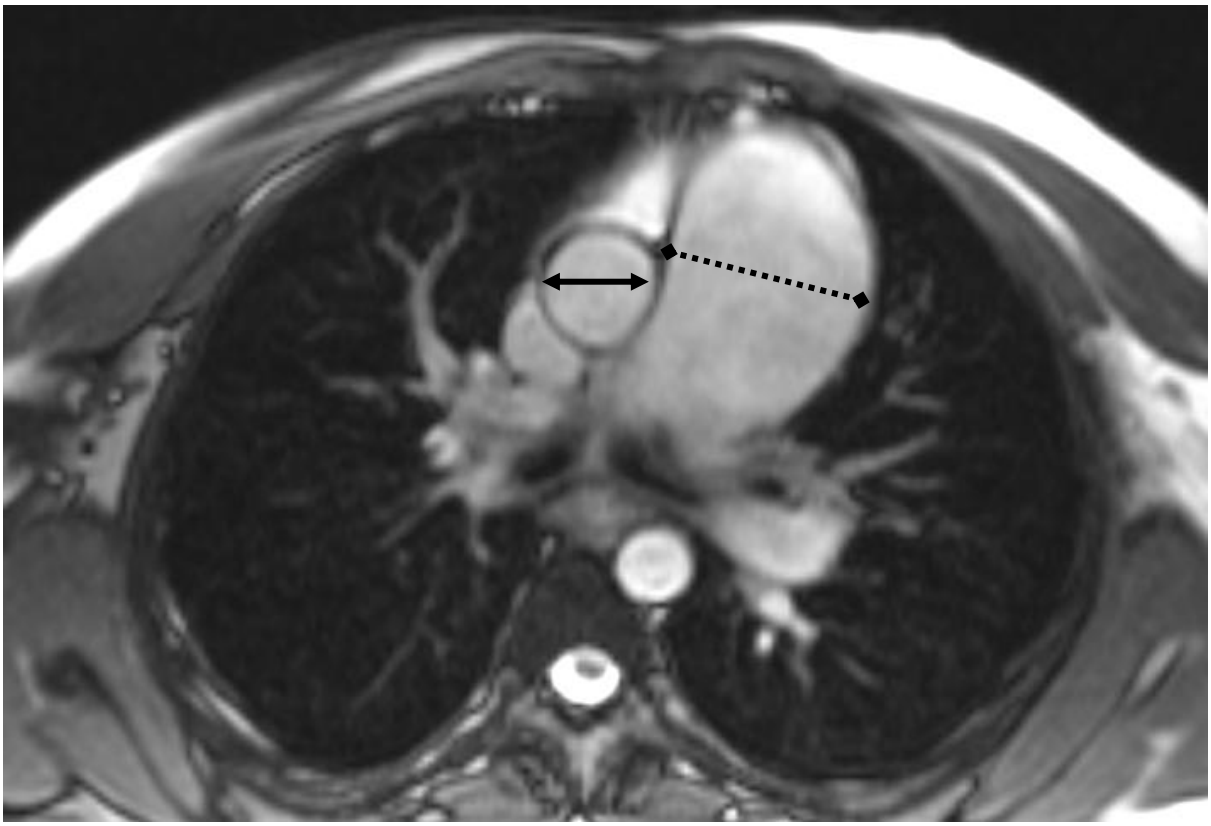
- Left ventricular eccentricity [sEI & dEI]. This is calculated on the short axis cine images midway between the base of the heart and the apex. Longitudinal distance of the left ventricle parallel to the interventricular septum is divided by the perpendicular distance from the midpoint of the interventricular septum to the lateral free wall. This measurement is obtained in systole and diastole and represents the movement of the interventricular septum in systole and diastole. This has also been shown to correlate with pulmonary hypertension (20).



- Figure 9. [a] and [b]
- Short axis views at mid-cavity level in [a] – systole and [b] – diastole.
- Eccentricity index is obtained by dividing the length of the vertical dotted line by the horizontal arrow.

▪ Late Gadolinium Enhancement at septal insertions probably represents ischaemic changes at the hinge points of the interventricular septum and are seen in pulmonary hypertension. However, this finding is non-specific ad may also be seen in other conditions such as hypertrophic cardiomyopathy.

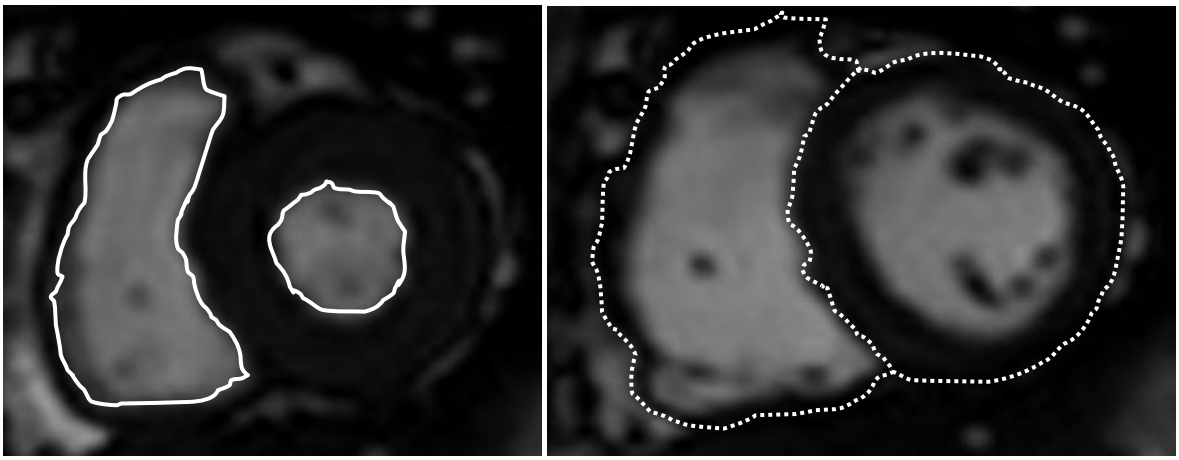
▪ A recent article published in the Journal of Cardiovascular Magnetic Resonance in the August 2015 edition proposes that the ratio of the diameter of the main pulmonary artery to the diameter of the aorta at that level correlates with pulmonary hypertension in patients with heart failure (21).



- Figure 9: TRUFISP axial section at the level of the pulmonary artery.

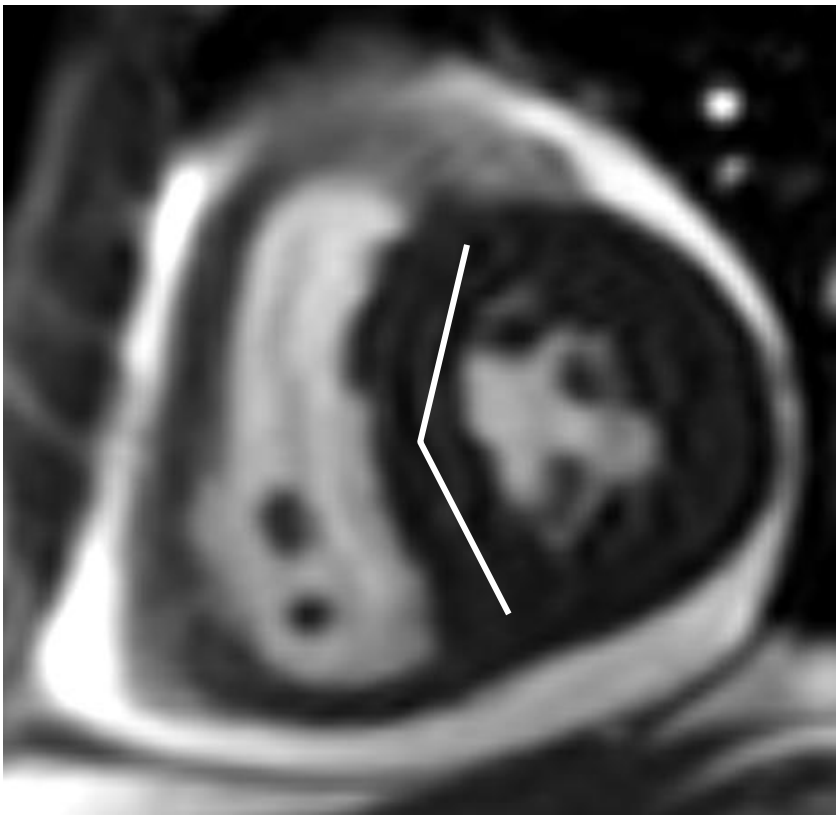
- Ratio of the length of the dotted line [MPA] over the straight arrow [Aorta] gives the Pulmonary artery: Aorta ratio.

- Cardiac MRI allows the delineation of the endocardial and epicardial borders at each section of the heart that allows the calculation of the muscle volume of the ventricles. When this is multiplied by the density of the heart muscle, one is thereby able to infer the myocardial mass of each ventricle. The interventricular septum is considered to be part of the left ventricle and is excluded and from the calculation of the right ventricular mass. The right and left ventricular masses thus computed may be divided by the body surface area to yield the indexed values. When the right ventricular mass is divided by the left ventricular mass, it yields a ratio called the Ventricular Mass Index [VMI]. Several studies have shown significant relationships between CMR parameters with mean pulmonary artery pressure [mPAP] and pulmonary vascular resistance [PVR] as measured on right heart catheterisation including ventricular mass index (VMI) (17,22–25).



- Figure 9. Short axis views at mid-cavity level in [a] – systole and [b] – diastole.
- Endocardium of both ventricles have been traced on the end systolic image while epicardium is traced on the end diastolic image (dotted lines)

- Inter Venricular Septal Angle. This is measured on the short axis images at the mid level in right ventricular systole. A line is drawn from the anterior and posterior hinge points of the right ventricular free wall to the midpoint of the interventricular septum. The angle formed between these two lines towards the left ventricle is measured. This angle becomes more obtuse with increase in right ventricular pressures. Several studies have shown significant relationships between mean pulmonary artery pressure [mPAP] and pulmonary vascular resistance [PVR] as measured on right heart catheterisation with the inter-ventricular septal configuration (26–28).



- Figure 10. Short axis view in systole demonstrating the measurement of angle of the interventricular septum

Phase contrast imaging

Phase contrast imaging also known as velocity encoded imaging has been used in Pulmonary Hypertension for pulmonary arterial blood flow quantification and plasticity. Through-plane velocity measurements are obtained from the main pulmonary artery and analysed using the post-processing software. This analysis will yield the following measurements for the pulmonary artery:

a) Peak velocity

b) Average velocity

c) Forward volume

d) Reverse volume

e) Minimum area of the pulmonary artery

f) maximum area of the pulmonary artery

From the above mentioned measurements, the following additional calculations can be made:

1) Forward volume – reverse volume = net forward volume. This corresponds to the right ventricular stroke volume

2) Reverse volume/ forward volume * 100 = percentage retrograde flow

3) Pulmonary artery distensibility = maximum area – minimum area of the pulmonary artery.

4) Maximum area – minimum area/ minimum area of the pulmonary artery = relative area change of the pulmonary artery

These values have been shown to have a high degree of correlation with mean pulmonary artery pressure (mPAP) and PVR measurements obtained at right heart catheterisation (24,29–32).

A large retrospective study has compared the multiple CMR parameters with Echocardiography and Right Heart Catheterisation and has shown sensitivity and specificity of up to 88% for some of these parameters (33).

Another recent large retrospective study has derived a formula to calculate mean pulmonary artery pressure (mPAP) from various right heart parameters measured on CMR:

CMR-predicted mPAP = - 4.6 + (interventricular septal angle x 0.23) + (ventricular mass index x 16.3) (34).

This formula suggests that the main factors affecting the pulmonary arterial pressures are those related to the right ventricular muscle mass in relation to that of the left ventricle and the interventricular septal bounce or bowing during systole. These measurements can therefore be made on the regular short axis CINE images acquired for the calculation of left ventricular ejection fraction on routine cardiac MRI. Consequently, these values may be computed retrospectively even if the patient was not known or suspected to have pulmonary hypertension at the time of imaging.

Patients and methods

Study Design: Study of Correlation

Study Type: Analytical and descriptional

Setting of study:

Christian Medical College (CMC) Vellore is a tertiary teaching hospital in Tamil Nadu, 80miles west of Madras. It was established in 1900 by Dr. Ida Sophia Scudder, a Christian Missionary from the United States of America to educate Indian women to treat Indians. It is now a Quaternary level referral centre with 2700 beds and around 8000 outpatients a day.

The Department of Radiology in CMC, Vellore was established in 1936 and became “filmless” in the year 2000 with the introduction of PACS (Picture Archival and Communication System). It functions as a single unit with approximately 75 radiologists and 20 postgraduates, over a hundred radiographers besides other staff.

Our department has two 1.5 tesla and one 3tesla MRI scanners. Approximately 3000 MRI examinations are performed every month including emergencies. Cardiac MRI is performed on the 1.5tesla SIEMENS machine and post-processed using the ARGUS software.

In the study period between July 2014 and August 2015, a total of 366 cardiac MRI examinations were performed, mostly for ischaemic heart disease.

Inclusion criteria:

1) Consecutive adult patients undergoing Right Heart Catheterisation for any indication during the study period.

2) Consecutive adult patients suspected with pulmonary hypertension on Cardiac MRI performed for any indication during the study period.

3) Those of the above who have a comparison Echocardiogram

Exclusion criteria:

1) Patients who have contra-indications for MRI such as MR incompatible implants, aneurysm clips or pacemakers

2) Paediatric patients who may require anaesthesia for Cardiac MRI

3) Patients who refuse cardiac MR

4) Those who do not have a comparison study, either an echocardiogram or right heart catheterisation

5) Those who have significant additional abnormality on cardiac MRI such as congenital heart disease or myocardial infarction that would interfere with accurate measurements on MRI

Methodology

Sampling & Consent

Pulmonary hypertension is relatively rare and right heart catheterisation for the same is even rarer. Therefore all patients who underwent right heart catheterisation for any indication, for whom pulmonary pressures were measured and who fulfilled the inclusion criteria were invited to participate in the study. No specific sampling strategy was employed to enroll such patients. However, many patients could not be included due to lack of machine time and competent personnel for performing the study. Informed written consent was obtained from the patient or patient's guardian prior to MRI.

Other patients who were suspected to have pulmonary hypertension after they had cardiac MRI on routine reporting were included retrospectively if they fulfilled the inclusion criteria and had none of the exclusion criteria. Consent was reckoned obtained by implication.

The consent form along with the Patient Information sheet is attached in Annexture section.

Cardiac MRI

(i) MRI scanner

Cardiac MRI was performed at our institution in a 1.5T scanner (Avanto, SIEMENS Systems, Germany). Patients were positioned supine in the head first position. They were connected to ECG leads and pulse oximetry throughout the period of image acquisition.

(ii) Coils

1.5T – 16 channel body array anterior MRI coils were used

(iii) MRI Sequence protocol

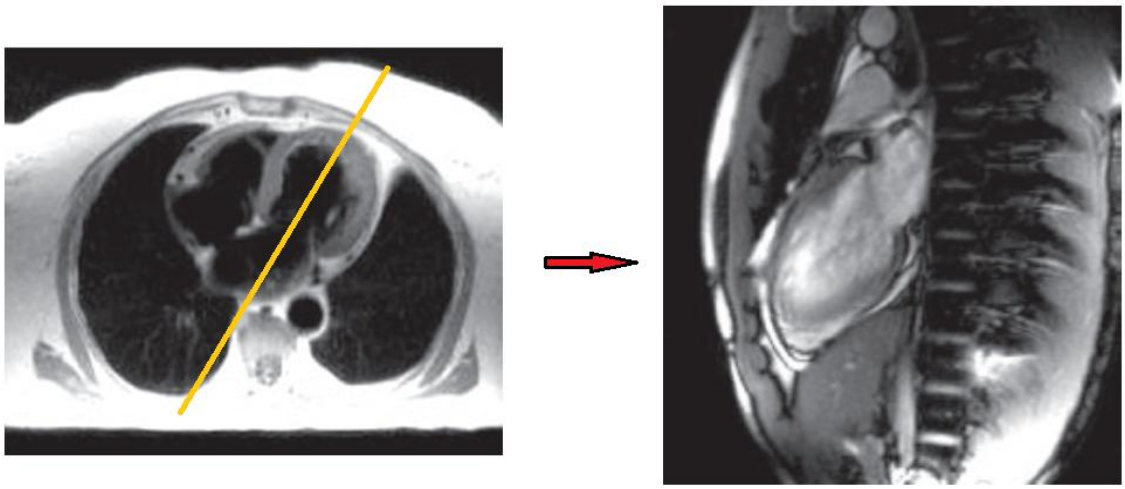
The MRI protocol included the following sequences

2D TRUFISP AXIAL OF THORAX

Field of view (FOV) was set at 400mm; slice thickness 6mm with slice gap of 1.2mm; TR (repetition time) of 161.83ms and TE (Echo time) of 1.17ms; Acquisition matrix 136 x 256. Imaging was performed with ECG triggering and breath holds. Acquisition window was 850. Trigger pulse was 1 with a trigger delay of 688. Scan time was 50 seconds with varying concatenations, depending on the patient's condition (concatenation – number of breath holds).

2 CHAMBER VIEW

A single slice is prescribed from the TRUFISP axial view. A line was drawn prescribed parallel to the ventricular septum bisecting the left ventricle through the mitral valve and apex to get a view consisting of 2 chambers, the left atrium and ventricle.



(a) (b)

Figure 11:

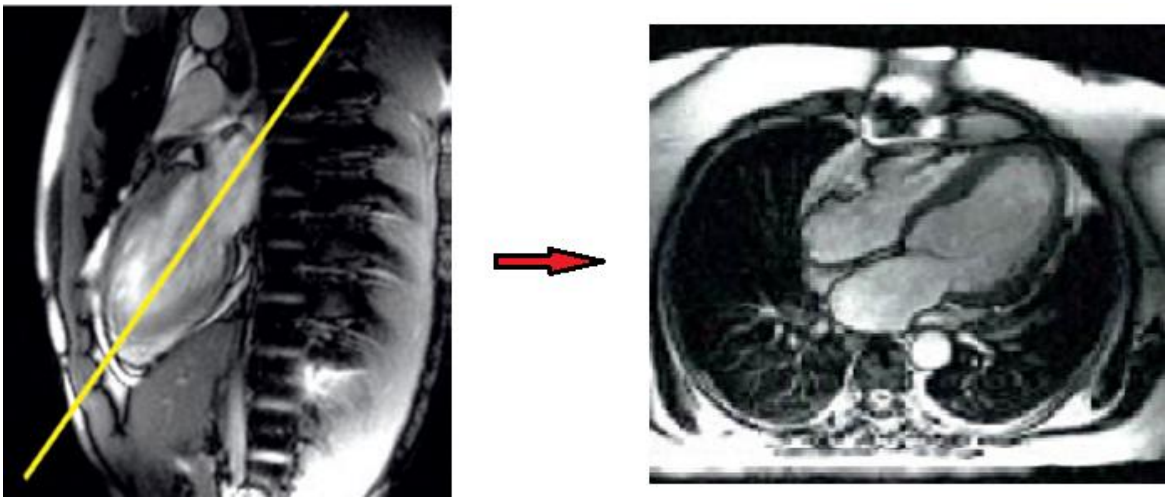
Obtaining the 2 chamber view.

(a) 2D TRUFISP axial through thorax

(b) 2 chamber view

4 CHAMBER VIEW

A slice was then prescribed from the 2 chamber view. A line was drawn bisecting the left ventricle through the mitral valve and apex to generate a view consisting of all the four chambers, the left atrium, left ventricle, right atrium and the right ventricle.



(a) (b)

Figure 12:

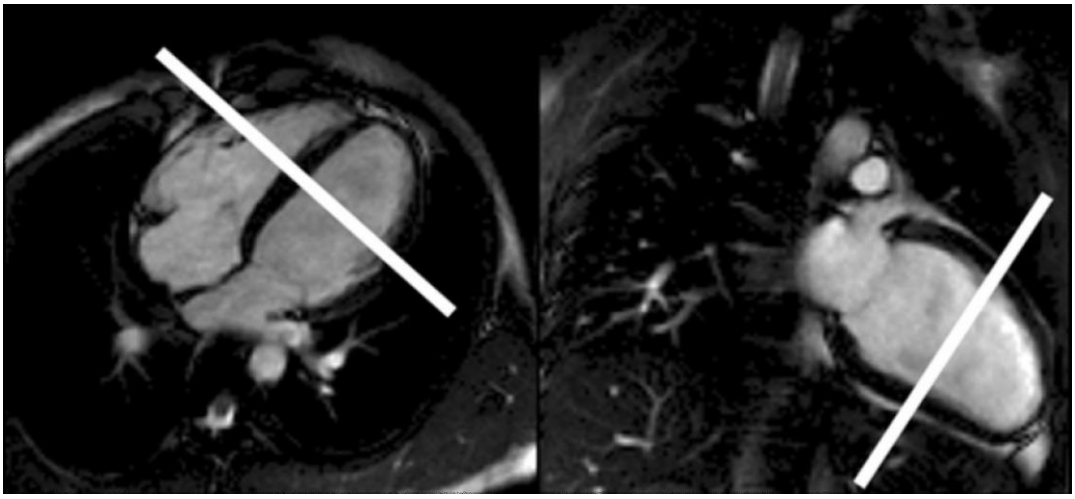
Obtaining the 4 chamber view.

(a) 2 chamber view

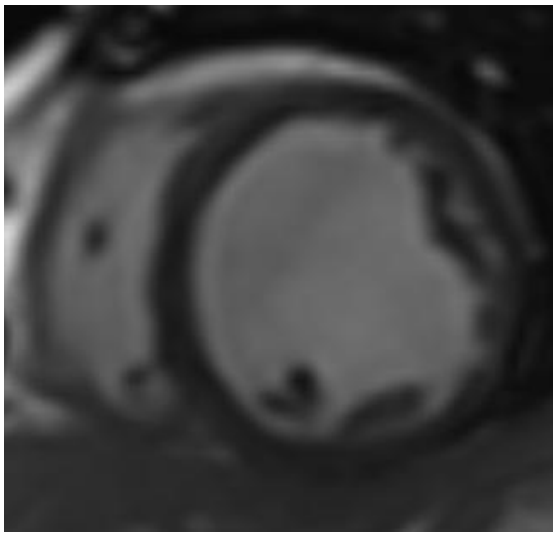
(b) 4 chamber view

SHORT AXIS SECTION

Stack of slices placed perpendicular to the long axis of the left ventricle were obtained from the mitral valve to the apex.



(a) (b)



(c)

Figure 13:

Obtaining the short axis view. (a) 4 chamber view (b) 2 chamber view (c) short axis view

Following this Phase-contrast imaging is performed through the main pulmonary artery to calculate velocity measurements. Velocity encoded [VENC] image acquisition with velocity adjustments ranging from 300 to 450 are obtained as through plane images of the main pulmonary artery. MAG images acquired simultaneously are sent along with the phase contrast images to the workstation as a data set.

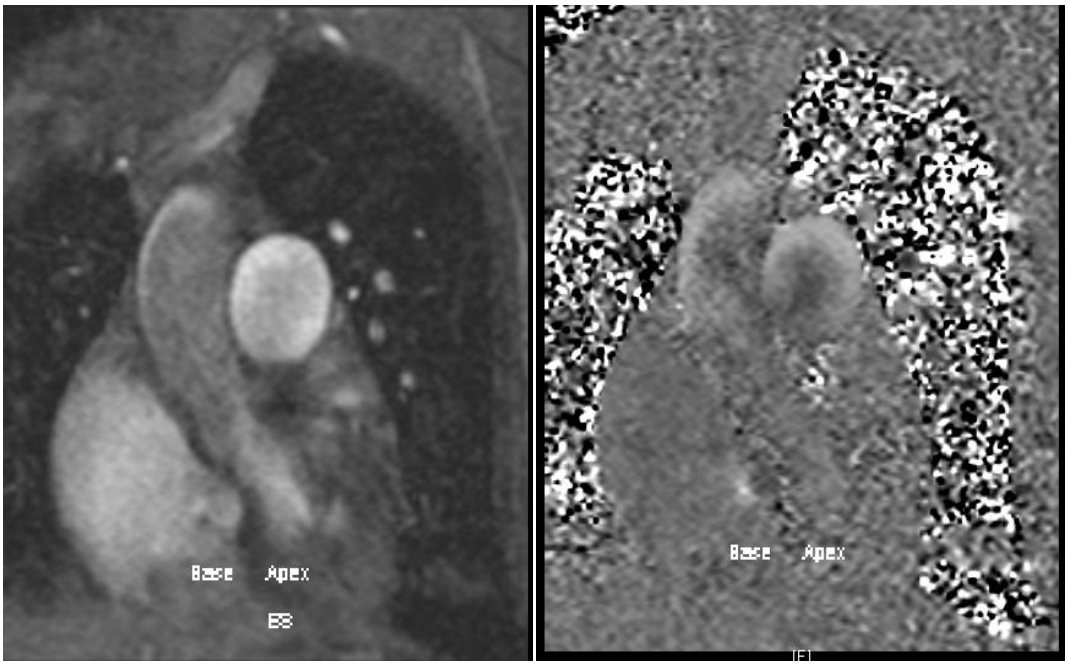


Figure 14.

Synchronised MAG & phase contrast images through the main pulmonary artery.

Summary of CMR sequences

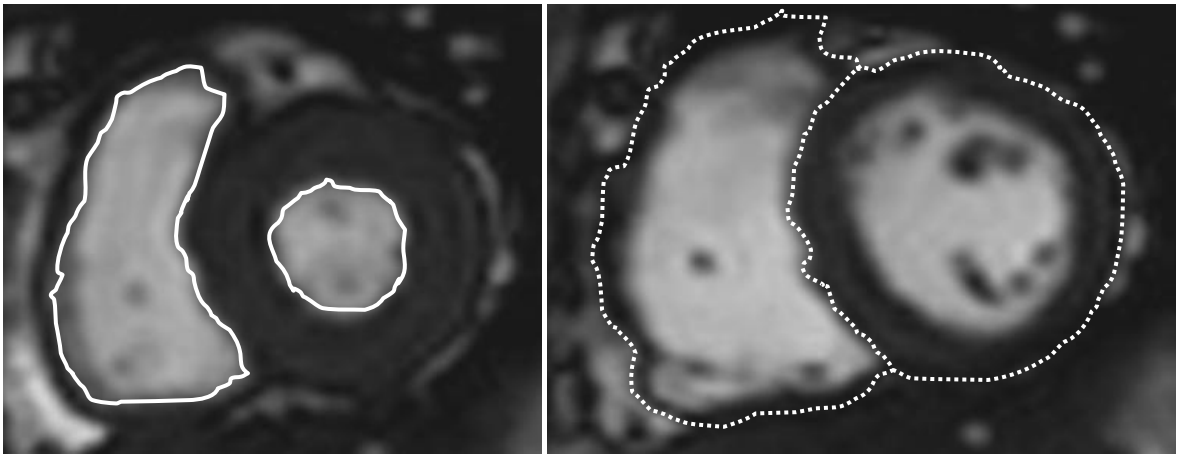
SSFP	True axial and short axis cine images
Phase contrast	Through plane velocity encoded images through the main pulmonary artery

(iv) Image Interpretation

1. Ventricular volumes and function:

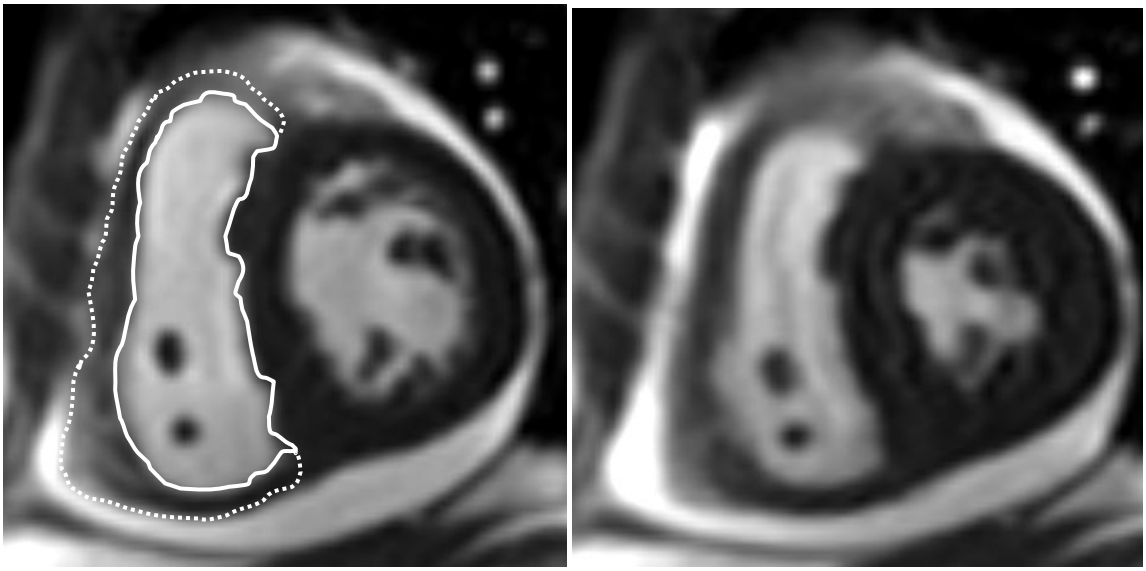
The ventricular volume and mass measurements will be calculated by the Siemens 1.5 T MRI machine specific software which is a dedicated software provided by the same company. The software used is Argus software (Siemens, Erlangen Germany AG) .This software is already validated, being used widely internationally and is approved by the SCMR (Society for Cardiac Magnetic Resonance Imaging)

The short axis cine images are loaded onto the ARGUS volumetric analysis application in the workstation that arrays the entire series of images from the cine stack in a grid, where mages proceed from base to apex along the rows and through the heart cycle along the columns. The End Diastole is usually selected by the software based on the ECG gating and is displayed along the first column. The software arbitrarily calculates the End Systole series which can be modified by the image interpreter through visual analysis. Once the End Diastole and End Systole have been ascertained, the outline of the endocardium and the epicardium are traced using the drawing tools provided by the software.



- Figure 15.
- Short axis views at mid-cavity level in [a] – systole & [b] – diastole.
- Endocardium of both ventricles have been traced on the end systolic image while epicardium is traced on the end diastolic image (dotted lines)

In the End diastole series, the epicardium and endocardium are traced for both the right and the left ventricles. The first section is selected where the ventricular wall is seen surrounding at least 50% of the cavity. If part of the aorta or the pulmonary artery is included in the image, these portions are excluded from the tracing. In the left ventricle, the papillary muscles and trabeculae are included within the endocardium according to convention. The inter-ventricular septum is included within the epicardial tracing for the left ventricle and excluded from the right ventricle according to convention. As much as is reasonably feasible, the trabeculations in the right ventricle are included as part of the right ventricular mass and not included within the endocardium. Tracings are drawn upto the apex.



- Figure 16.
- Short axis views at mid-cavity level in [a] – diastole & [b] – systole in a patient with pulmonary hypertension and mild pericardial effusion
- Endocardium and epicardium(dotted lines) of the right ventricle is traced on the end diastolic image
- Note that the interventricular septum forms part of the left ventricular wall and is hence not included in the right ventricle mass.

In the End systole series, the endocardium alone is traced for both the right and left ventricles as stated above, from the base to the apex, excluding portion of the aorta and the pulmonary artery.

2. The ARGUS software then analyses the tracings and analysis will yield the following measurements for right and left ventricles separately:

a) Ventricular end diastolic volume [EDV] obtained by multiplying the sum of the areas within the endocardial outline by slice thickness at End Diastole

b) Ventricular end systolic volume [ESV] obtained by multiplying the sum of the areas within the endocardial outline by slice thickness at End systole

c) Ventricular mass at end diastole, which is obtained by multiplying ventricular myocardial volume at end diastole by 1.05 [specific gravity of cardiac myocardium]. The ventricular myocardial volume is obtained by multiplying with slice thickness with the sum of areas between the endocardial and epicardial tracings.

3. From the above measurements, the following additional calculations are generated by the software for both ventricles:

b) Stroke volume [SV] = EDV – ESV

c) Ejection fraction = EDV – ESV/ EDV

d) Indexed ventricular volumes and masses obtained by dividing the desired value by the patient’s body surface area.

4. The following additional measurements and calculations that are not provided by the software are also made:

a. Interventricular septal angle. This is measured in the systolic phase midway between the base of the heart and the apex. A line is drawn connecting the anterior and posterior hinge points with the midpoint of the setum. The angle sustained between these two lines is the interventricular septal angle.

b. Systolic eccentricity index [sEI]. This is measured in the systolic phase midway between the base of the heart and the apex. A line is drawn from the midpoint of the inter-ventricular septum perpendicularly towards the lateral wall and the distance between the endocardial surfaces is measured as D1. The longest transverse axis perpendicular to this line is also measured along a line parallel to the interventricular septum as D2. Eccentricity index is obtained by dividing D1 by D2.

c. Diastolic eccentricity index [dEI]. This is measured similar to the above in the diastolic phase.

d. Ventricular mass index [VMI]. This ratio is obtained by dividing the right ventricular mass in diastole by the left ventricular mass in diastole.

5. Phase contrast images through the pulmonary artery will be analysed using the Siemens 1.5 T MRI machine specific software which is dedicated software provided by the same company. The software used is Argus software (Siemens, Erlangen Germany AG) .This software is already validated, being used widely internationally and is approved by the SCMR (Society for Cardiac Magnetic Resonance Imaging). Pulmonary artery outline in cross-section is traced throughout the cardiac cycle on MAG images and these are then projected onto the phase contrast images. This analysis will yield the following measurements:

a) Peak velocity in the pulmonary artery.

b) Average velocity in the pulmonary artery.

c) Forward volume in the pulmonary artery.

d) Reverse volume in the pulmonary artery.

e) Minimum area of the pulmonary artery

f) maximum area of the pulmonary artery

6. From the above mentioned measurements, the following additional calculations are made:

a) Forward volume – reverse volume = net forward volume. This corresponds to the right ventricular stroke volume

b) Reverse volume/ forward volume * 100 = percentage retrograde flow

c) Maximum area – minimum area/ minimum area of the pulmonary artery = relative area change of the pulmonary artery

The Argus software also generates the following analysis from flow studies:

1. Flow vs. time curve

2. Velocity vs. time curve

3. Area vs. time curve

4. Peak flow vs. time curve

5. Peak velocity vs. time curve

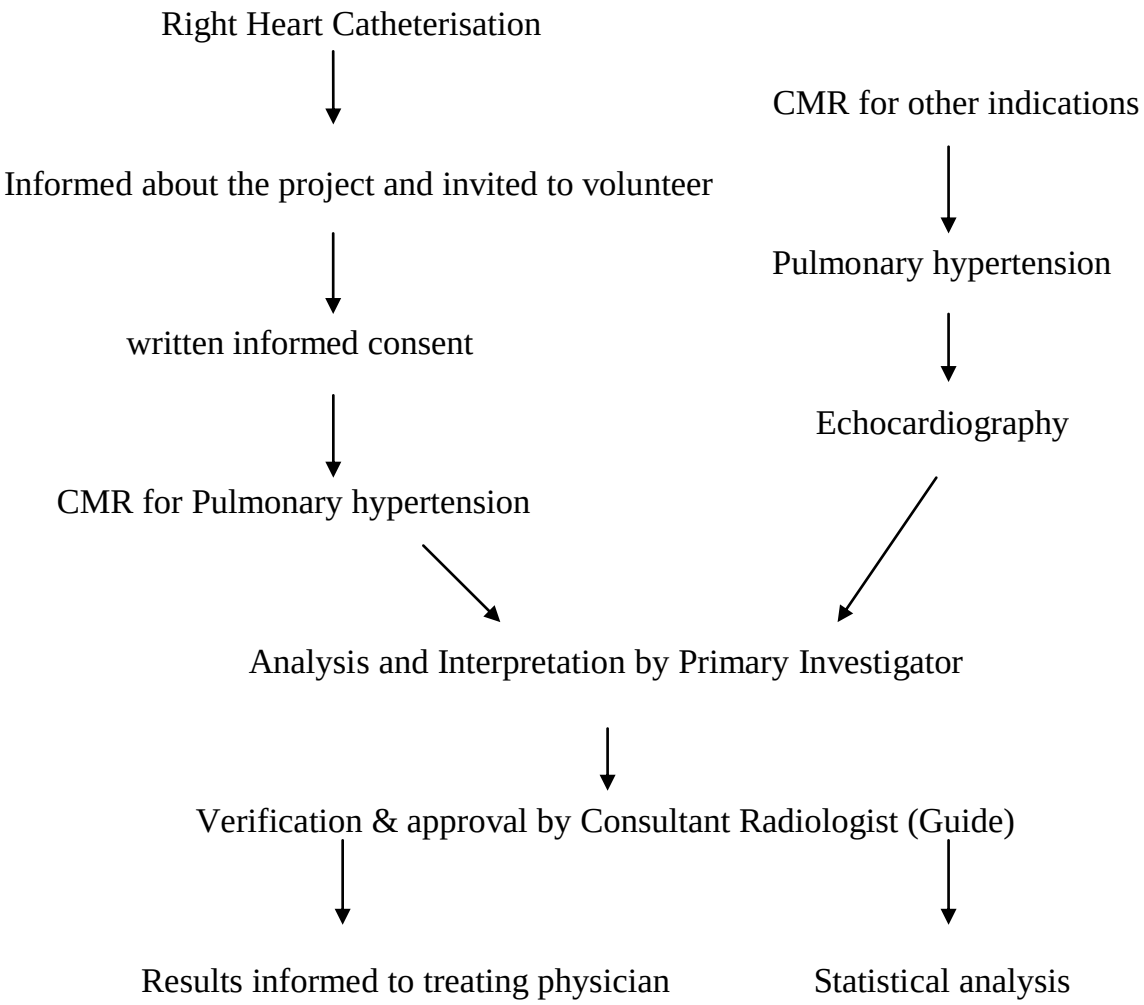
CMR-predicted mean pulmonary artery pressure (mPAP) is then calculated from various right heart parameters using the formula which has been deducted in a recent large multicentric retrospective study as mentioned in the literature review.

CMR-predicted mPAP = -4.6 + (IVS angle x 0.23) + (VMI x 16.3)

Where mPAP stands for mean pulmonary arterial pressue, IVS for interventricular septum and VMI for ventricular mass index.

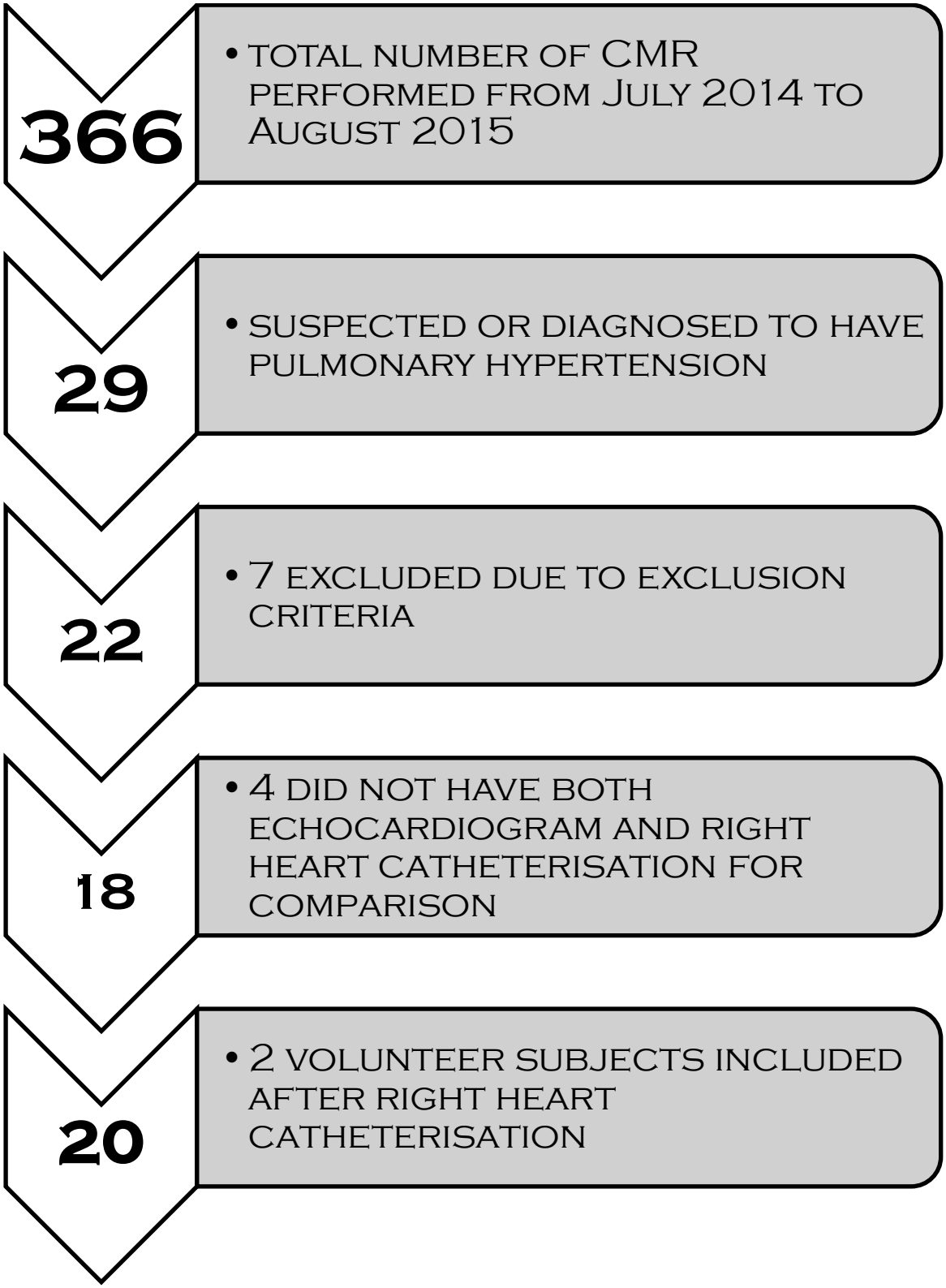
Each of the above parameters is then compared against the mean pulmonary artery pressure (mPAP) measured on Echocardiogram and right heart catheterisation when available.

Detailed diagrammatic Algorithm of the study



Analysis and results

Chart demonstrating the enrollment of subjects in the study



Demographic data:

Total number of subjects who were analysed: 20 adults

Men - 65%

Women – 35%

Gender distribution:

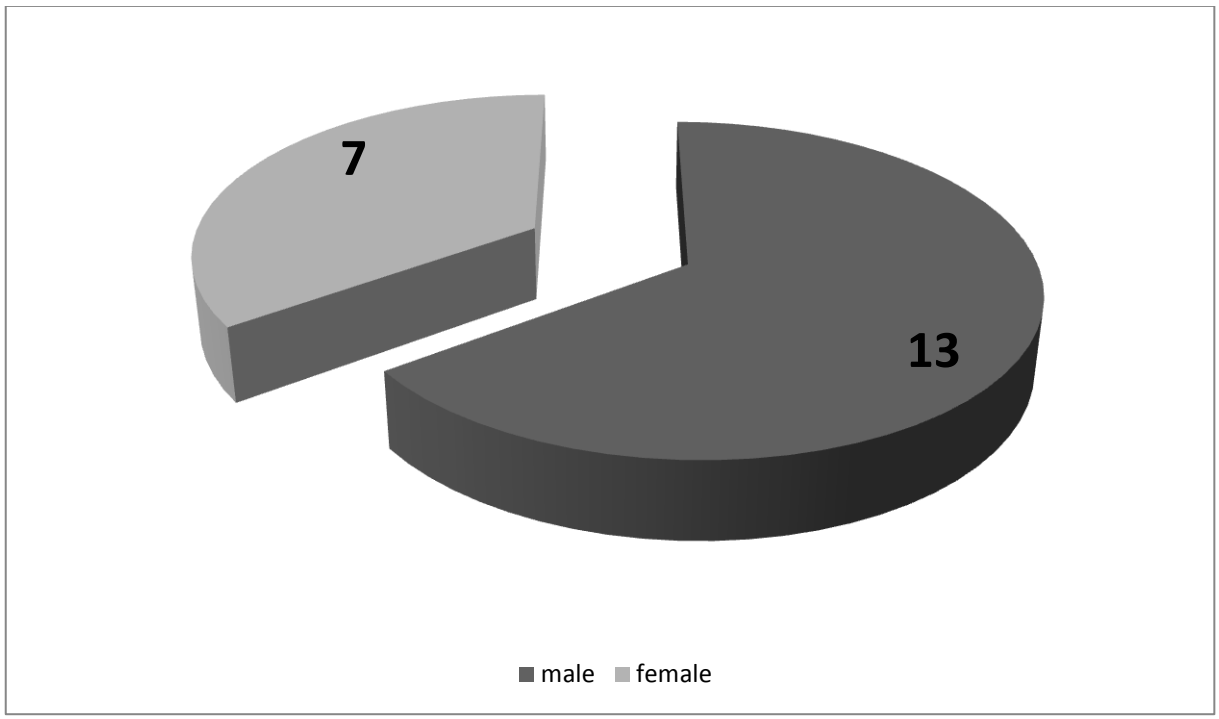


Figure 17

Age distribution:

Mean		45.30
Median		48.00
Std. Deviation		12.876
Minimum		23
Maximum		63
Percentiles	25	32.50
	50	48.00
	75	57.25

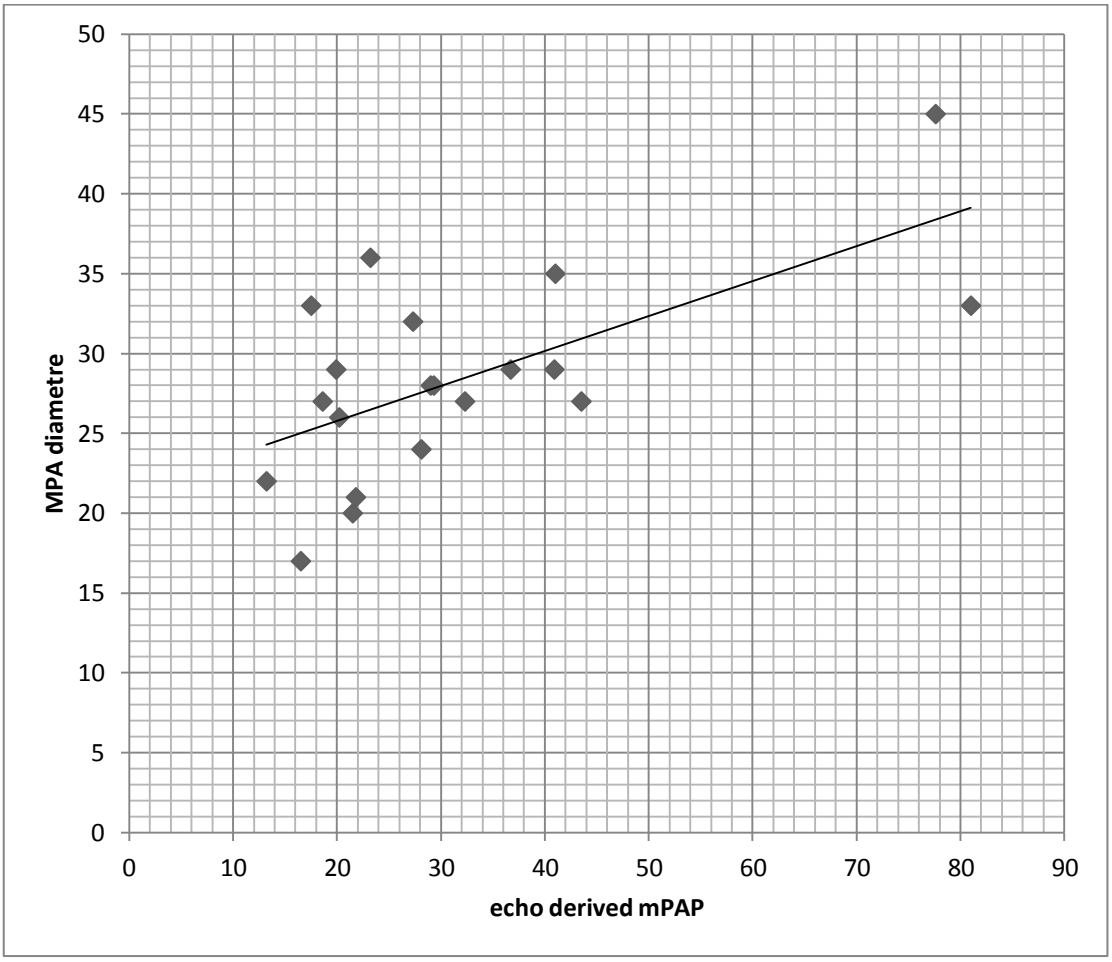
Echocardiogram parameters:

At least half of those analysed had pulmonary hypertension according to pressures measured on Echocardiography

Statistics

		Tricuspid regurgitant jet velocity	Pressure gradient across the tricuspid valve	Pulmonary artery systolic pressure	Mean pulmonary arterial pressure
Mean		311.990	42.990	49.140	31.955
Median		290.000	33.750	42.050	27.700
Std. Deviation		99.5152	30.2190	30.1800	18.3668
Minimum		183.0	13.4	18.4	13.2
Maximum		559.0	125.0	130.0	81.0
Percentiles	25	238.750	22.825	29.500	19.975
	50	290.000	33.750	42.050	27.700
	75	356.325	54.275	61.975	39.850

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram & MPA diameter on CMR



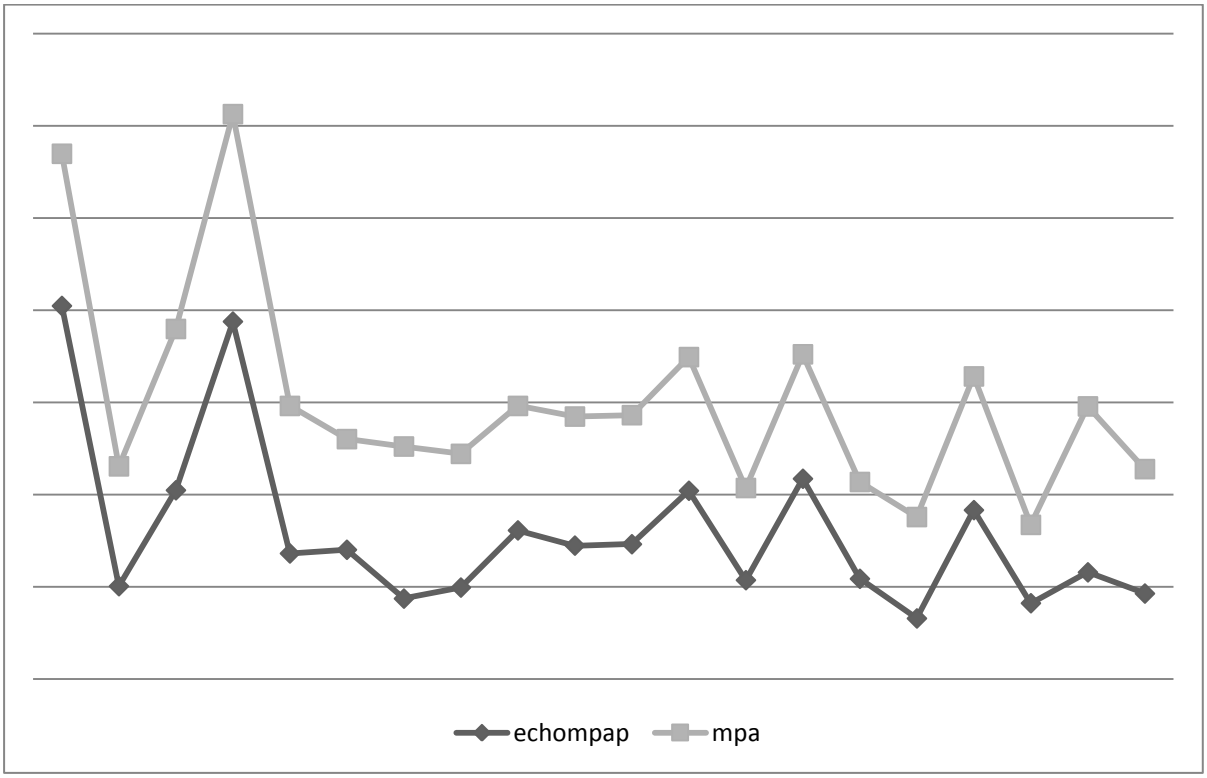
Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

Main pulmonary artery diameter is expressed in mm.

Pearson's co-efficient of correlation = 0.635

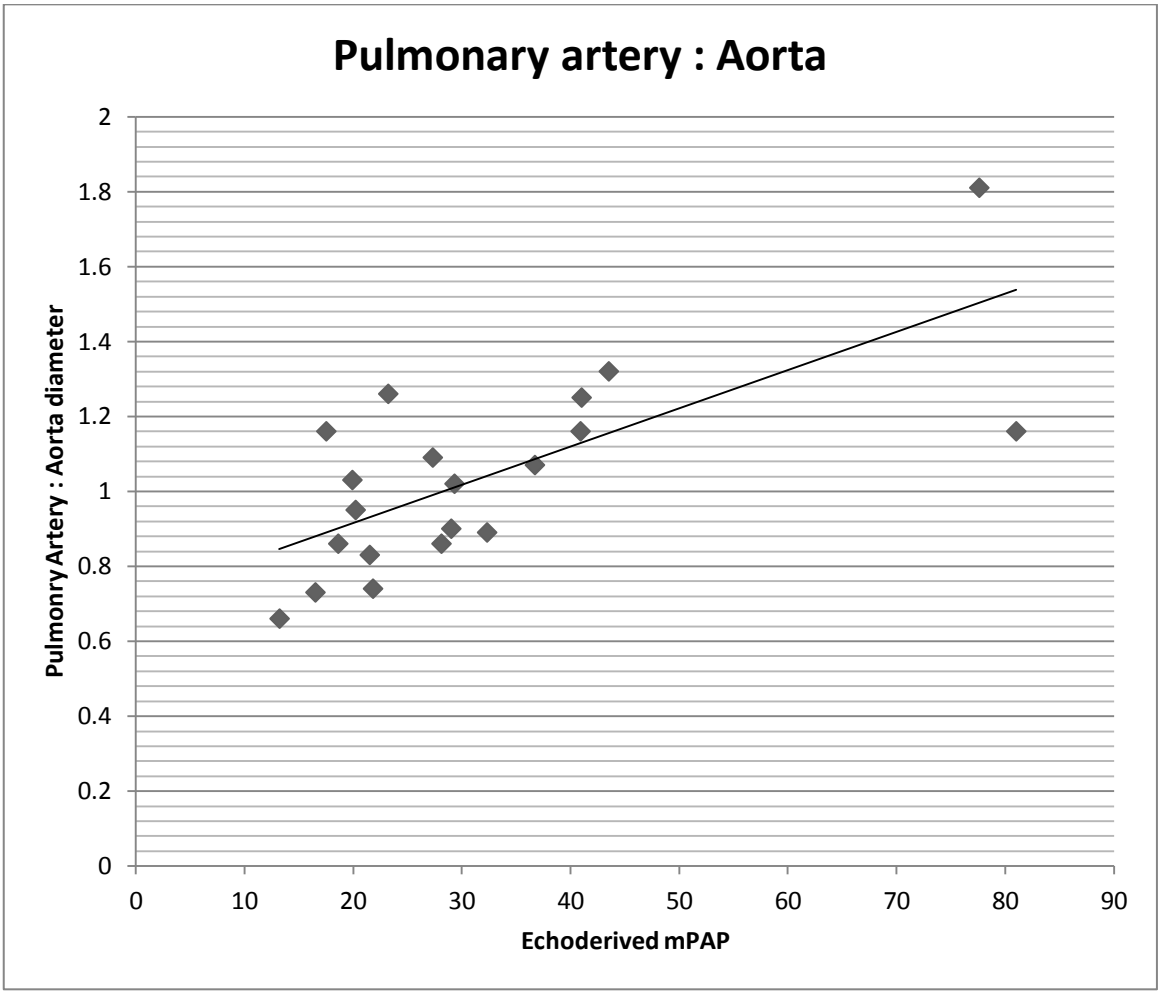
Significance (p value) = 0.003

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram & MPA diameter on CMR



This chart shows the near total overlap of the curves suggesting a fairly high degree of correlation between the values even in the absence of pulmonary hypertension; i.e., normal individuals.

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram and ratio of the diameter of main pulmonary artery to that of ascending Aorta at the same level as measured on CMR



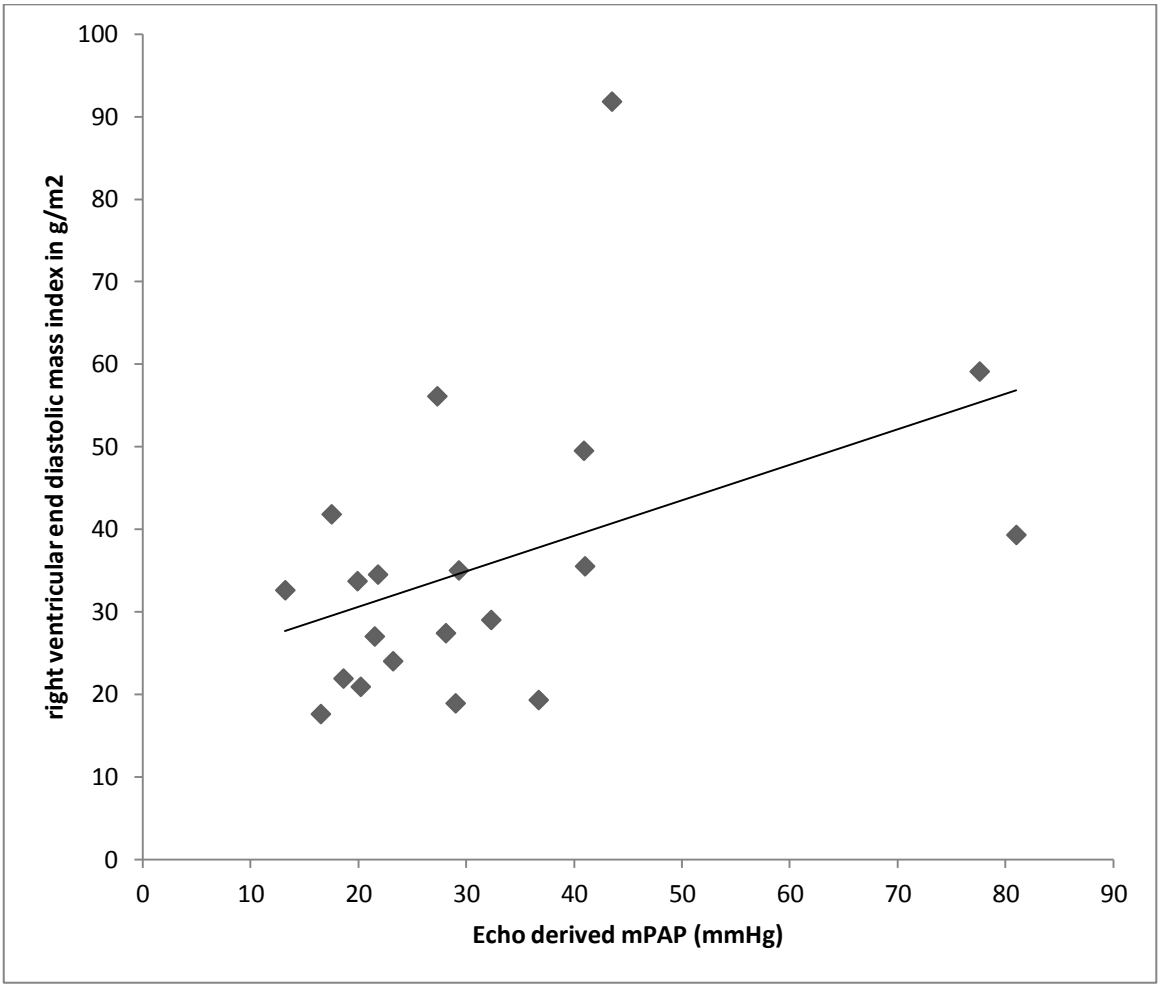
Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

Ratio of main pulmonary artery diameter to diameter o the aorta is on y axis.

Pearson's co-efficient of correlation = 0.716

Significance (p value) = less than 0.001

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram & indexed right ventricular mass at end diastolic measured on CMR



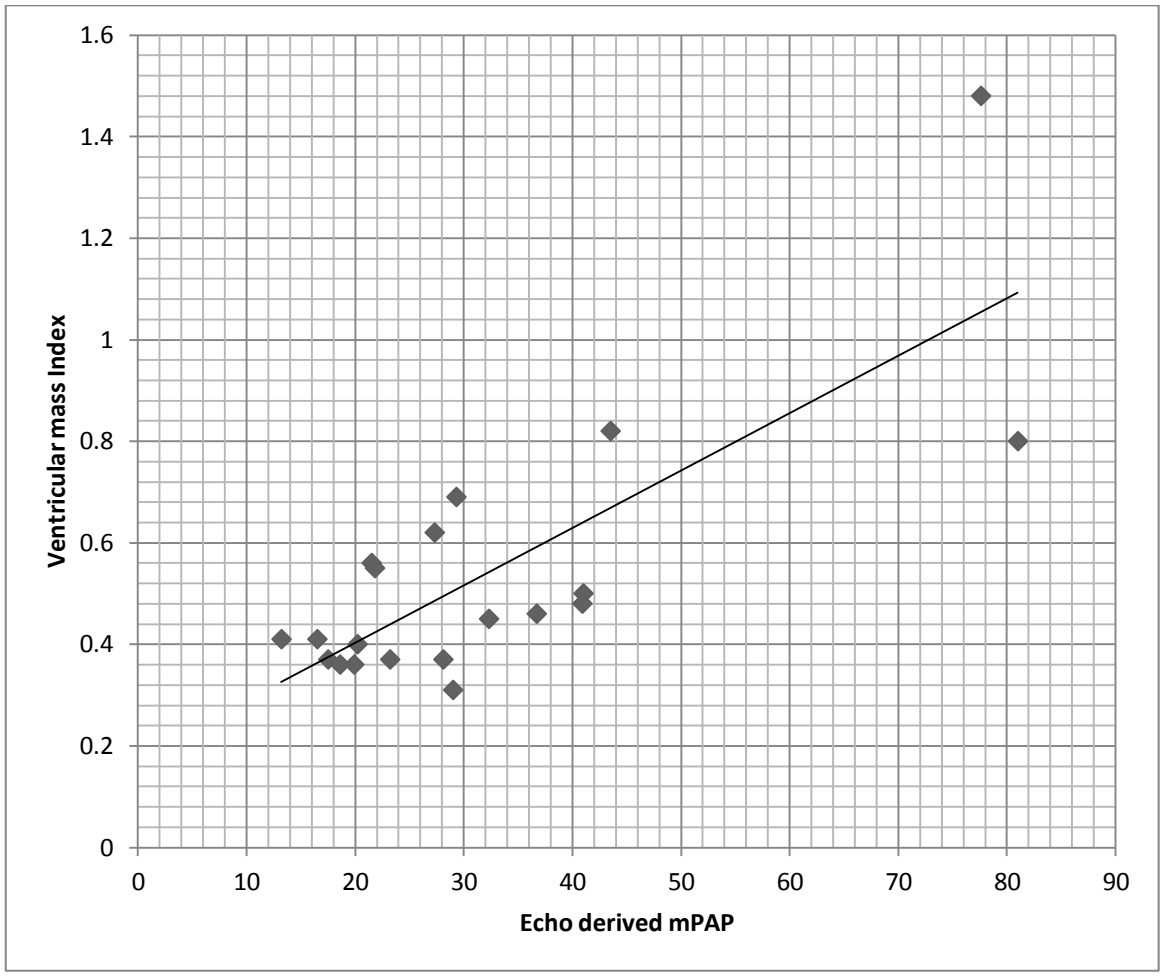
Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

Right ventricular end diastolic mass index is expressed in g/m2

Pearson's co-efficient of correlation = 0.446

Significance (p value) = 0.049

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram and ventricular mass index [VMI] computed from measurements on CMR



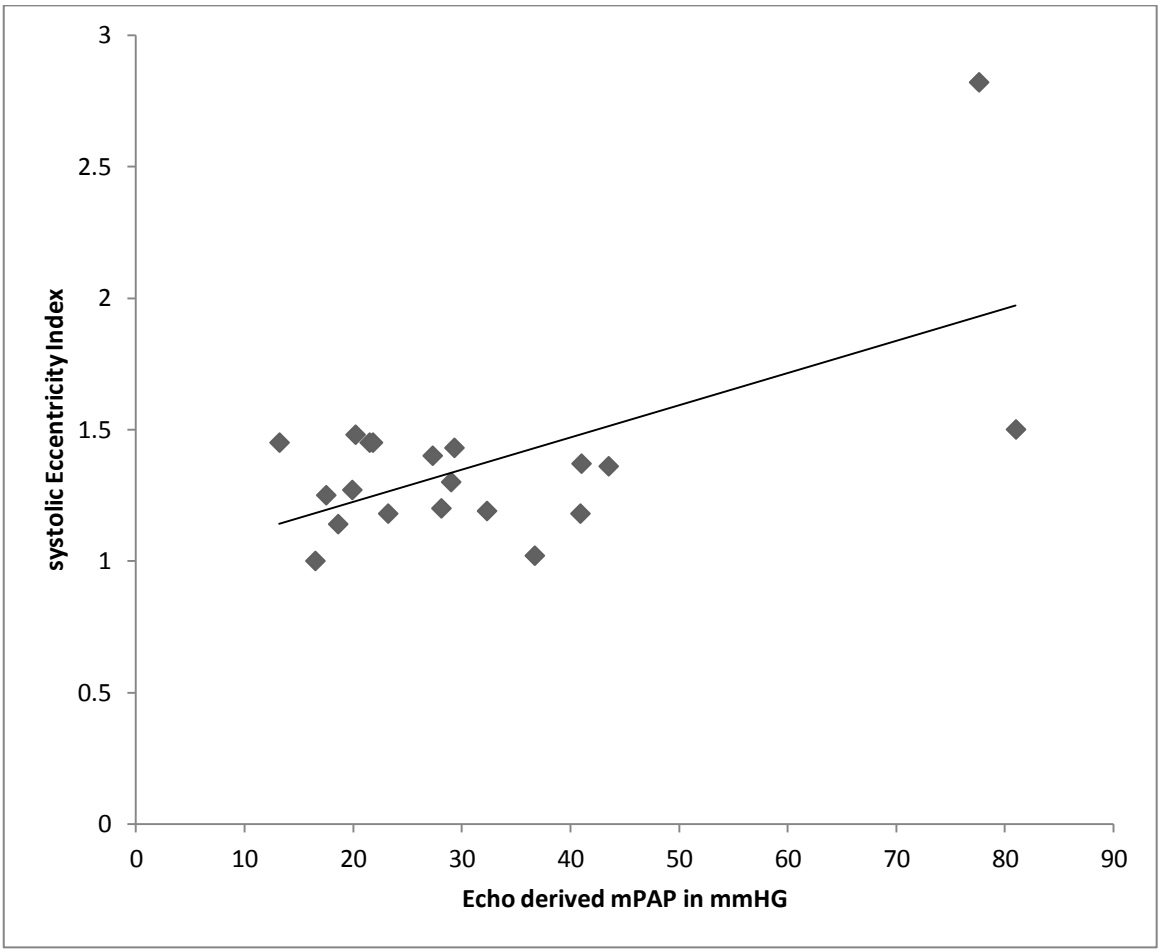
Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

Ventricular mass index is expressed as a ratio.

Pearson's co-efficient of correlation = 0.783

Significance (p value) = less than 0.001

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram and systolic eccentricity index [sEI] computed from measurements on CMR



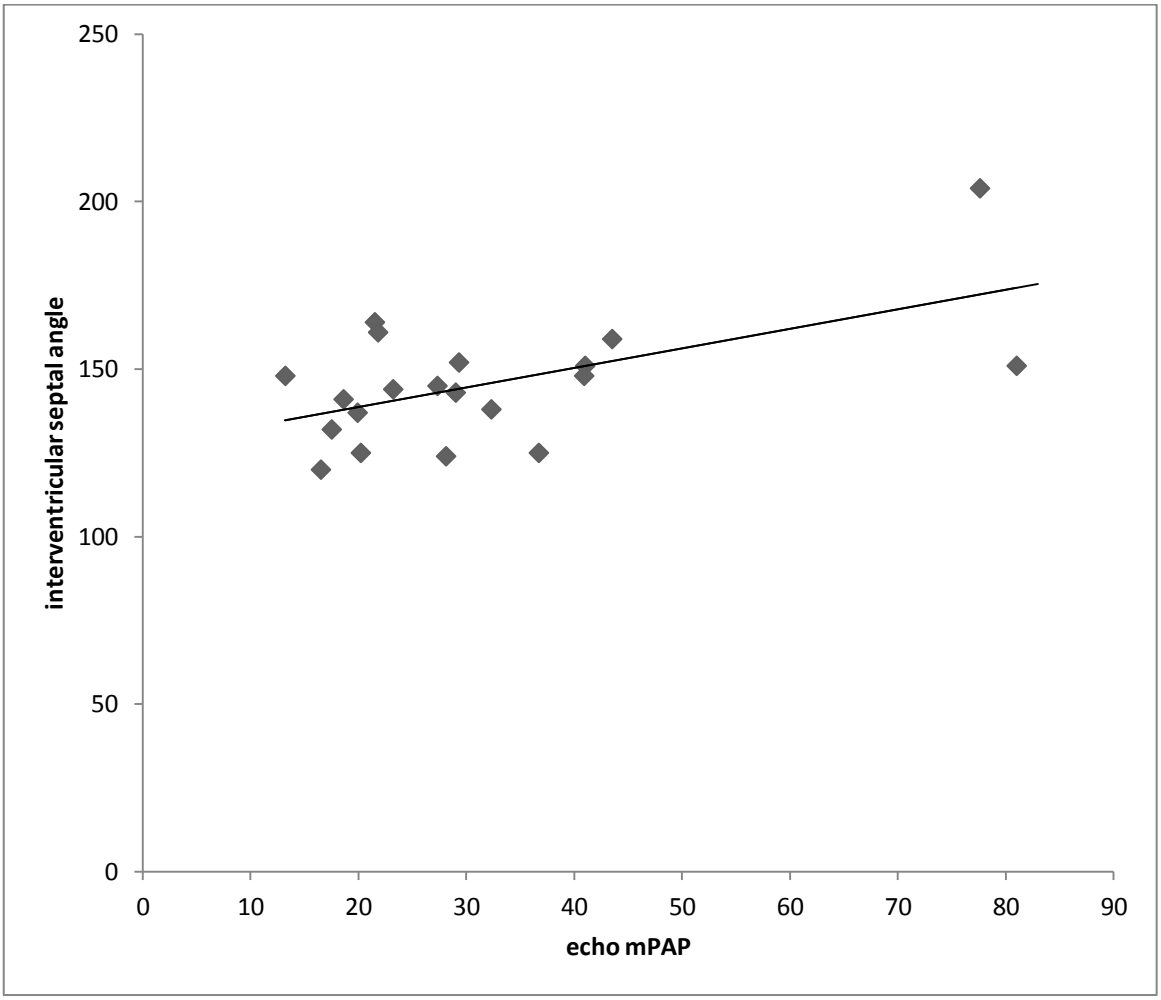
Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

Systolic eccentricty index is expressed as a ratio.

Pearson's co-efficient of correlation = 0.605

Significance (p value) = 0.005

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram and inter-ventricular septal angle measured on CMR



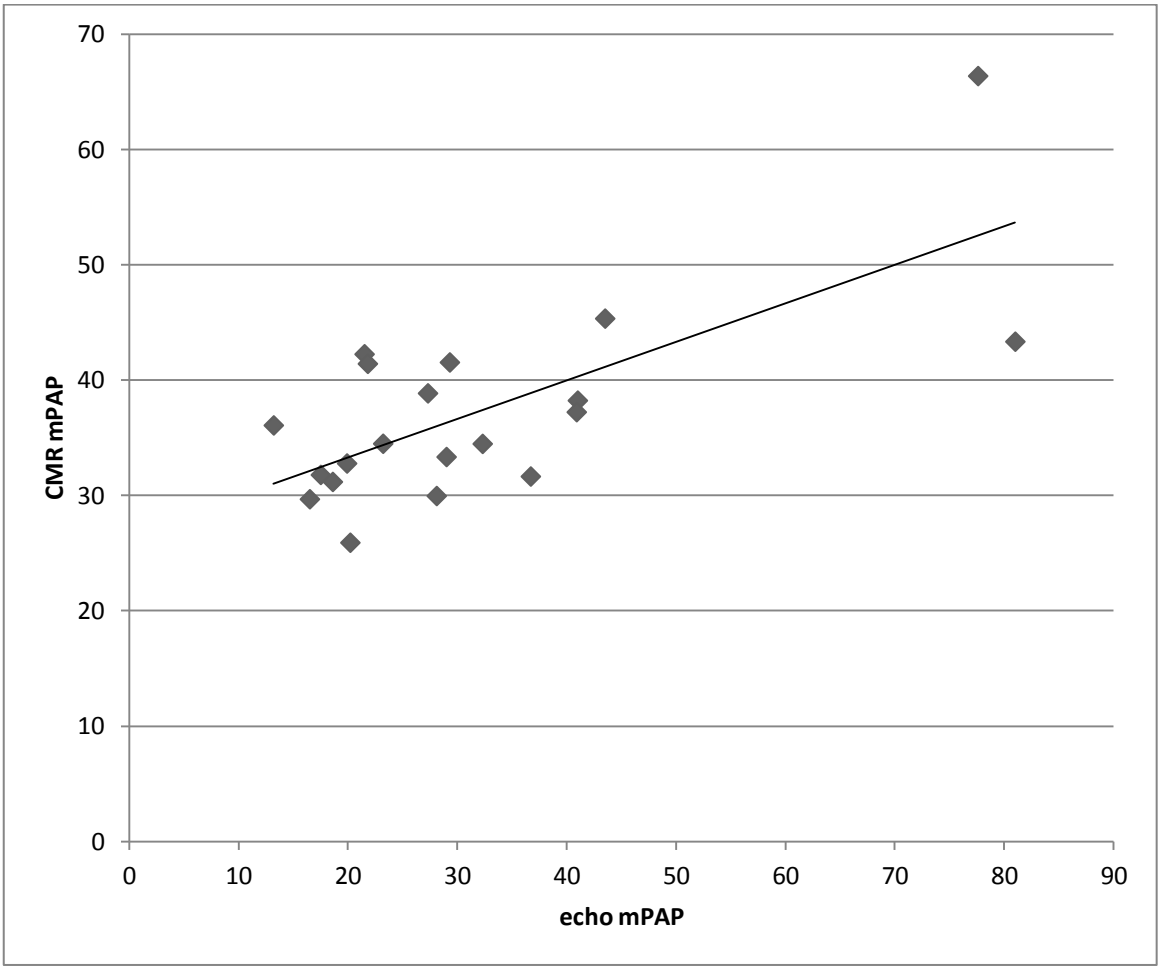
Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

Inter-ventricular septal angle is expressed on the y axis.

Pearson's co-efficient of correlation = 0.577

Significance (p value) = 0.008

Correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram and that derived from parameters measured on CMR



Echocardiogram derived mean Pulmonary artery pressure is expressed in mmHg.

CMR derived mean Pulmonary artery pressure is expressed in mmHg.

Pearson's co-efficient of correlation = 0.713

Significance (p value) = less than 0.001

Correlation of CMR parameters with mean pulmonary artery pressure (mPAP) measured on Echocardiography and their significance

CMR Parameter	Pearson correlation	Significance
Right ventricular ejection fraction	-0.189	0.426
Right ventricular end diastolic volume	0.169	0.477
Right ventricular end systolic volume	0.188	0.427
Right ventricular stroke volume	0.102	0.669
Right ventricular mass in end diastole	0.431	0.058
Right ventricular end diastolic volume index	0.19	0.421
Right ventricular end systolic volume index	0.199	0.4
Right ventricular stroke volume index	0.14	0.555
Left ventricular ejection fraction	0.108	0.649
Left ventricular end diastolic volume	-0.15	0.528
Left ventricular end systolic volume	-0.056	0.816
Left ventricular stroke volume	-0.172	0.467
Left ventricular mass in end diastole	-0.235	0.319
Left ventricular end diastolic volume index	-0.14	0.556
Left ventricular end systolic volume index	-0.055	0.818
Left ventricular stroke volume index	-0.15	0.529
Left ventricular mass index	-0.217	0.359
Diastolic eccentricity index	**.492***	**0.028**

Multivariate analysis of the CMR parameters whose correlation with Echocardiogram derived mean pulmonary artery pressure (mPAP) was statistically significant

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	23.636	40.406		.585	.568
	Pulmonary Artery to Aorta Diameter Ratio	20.951	15.276	.298	1.372	.192
	Ventricular mass index	42.555	56.179	.614	.757	.461
	Systolic eccentricity index	-10.097	19.109	-.205	-.528	.605
	Interventricular septal angle	-.451	.808	-.457	-.558	.586
	CMR derived mPAP	1.157	2.720	.542	.425	.677

Though the above parameters were individually significant, multivariate analysis was not significant.

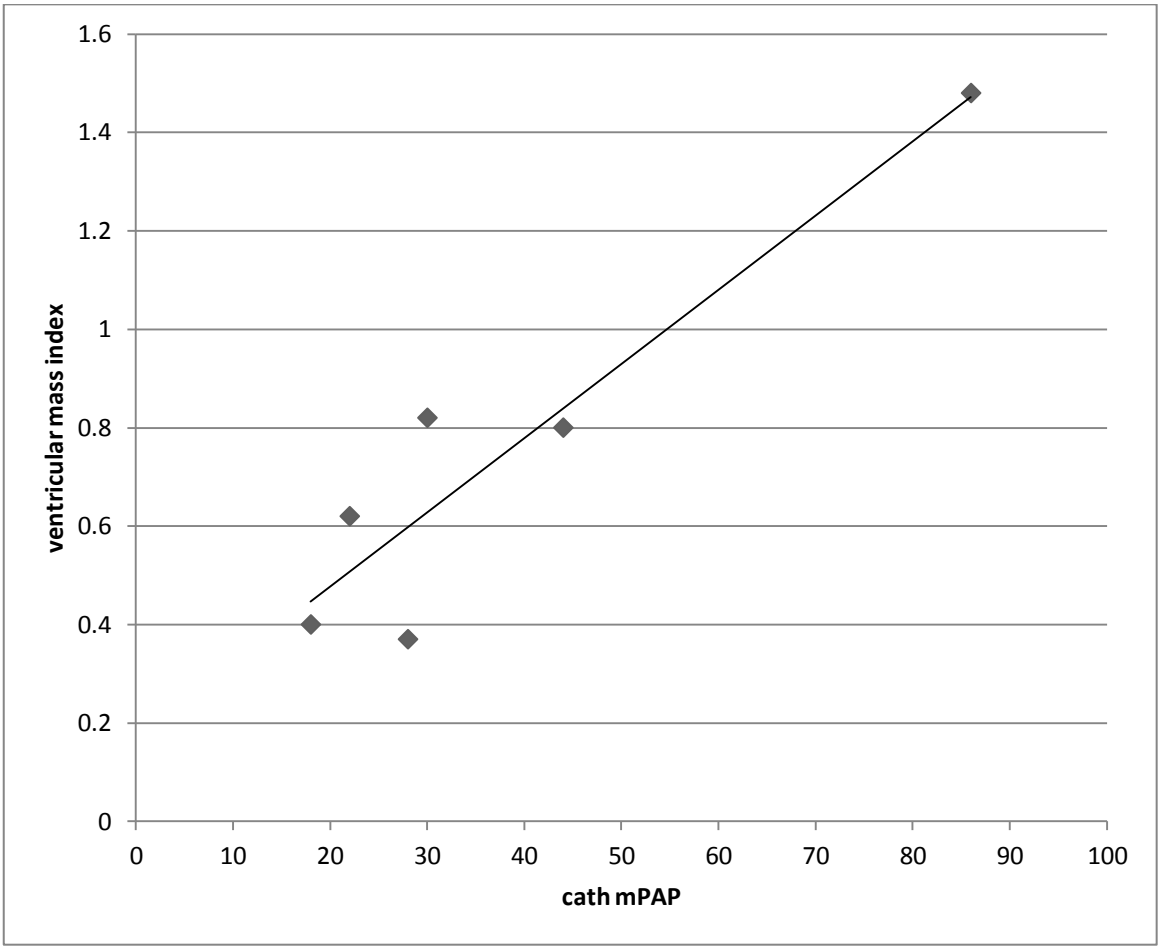
Right heart catheterisation measurements

Of the 20 subjects studied, 6 patients underwent right heart catheterisation.

Statistics

		Age of the patient	Peak systolic pressure	Diastolic pressure	mPAP
Mean		45.30	61.000	25.833	38.0000
Median		48.00	40.500	20.000	29.0000
Std. Deviation		12.876	45.2593	16.4124	25.13961
Minimum		23	31.0	12.0	18.00
Maximum		63	149.0	57.0	86.00
Percentiles	25	32.50	34.000	15.000	21.0000
	50	48.00	40.500	20.000	29.0000
	75	57.25	89.750	36.750	54.5000

Correlation between mean pulmonary artery pressure (mPAP) measured on right heart catherisation and ventricular mass index computed from measurements on CMR



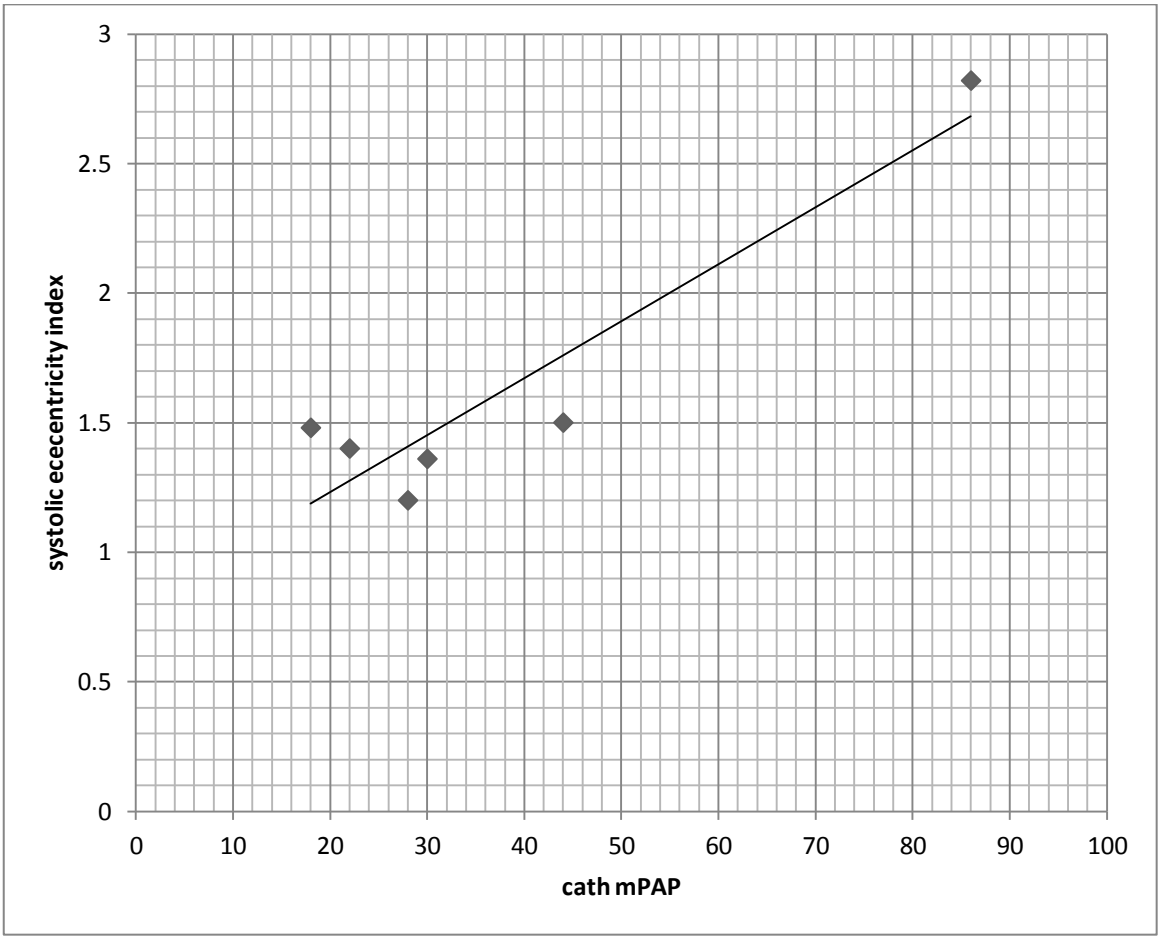
Right heart catherisation derived mean Pulmonary artery pressure is expressed in mmHg.

Ventricular mass index is represented as a ratio on the y axis.

Pearson's co-efficient of correlation = 0.934

Significance (p value) = 0.006

Correlation between mean pulmonary artery pressure (mPAP) measured on right heart catherisation and systolic eccentricity index computed from measurements on CMR



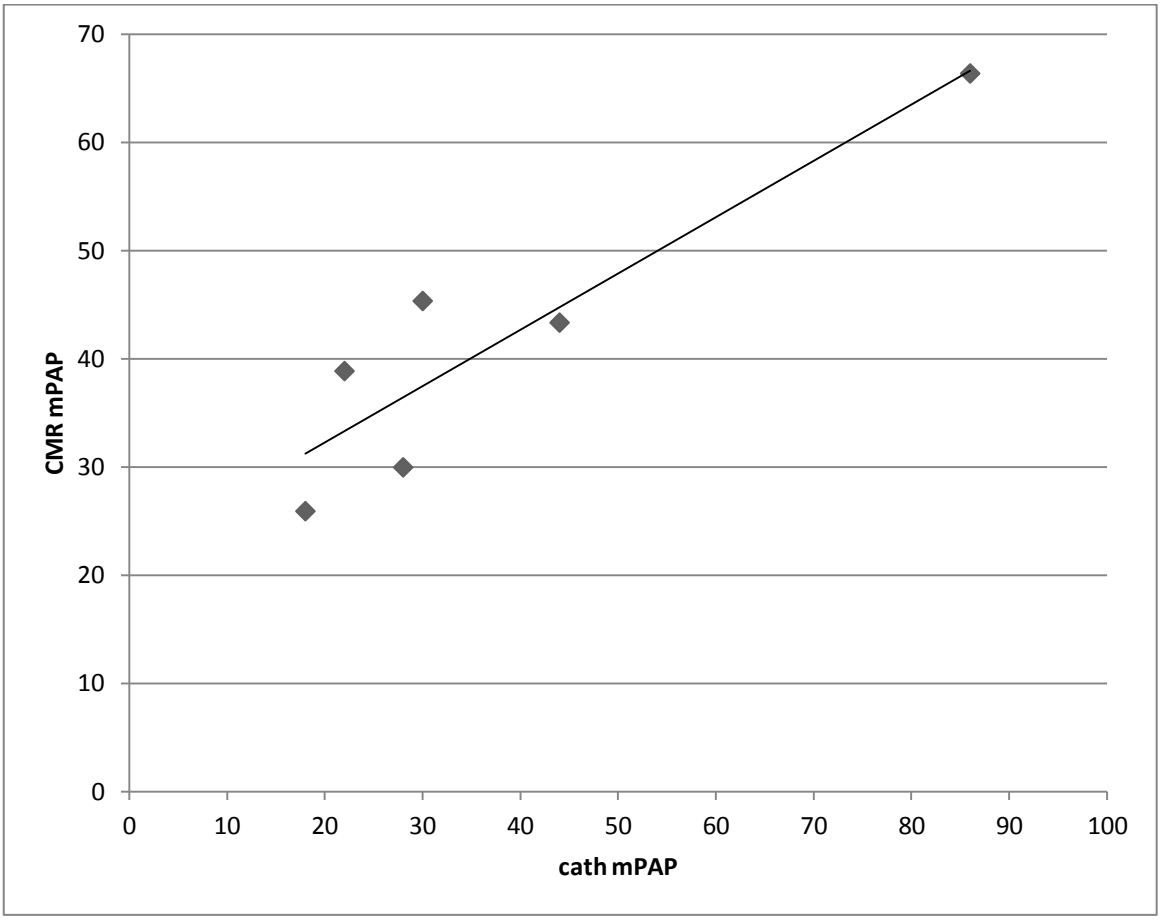
mean Pulmonary artery pressure measured on Right heart catherisation is expressed in mmHg.

Systolic eccentricity index is represented as a ratio on the y axis.

Pearson's co-efficient of correlation = 0.93

Significance (p value) = 0.007

Correlation between mean pulmonary artery pressure (mPAP) measured on right heart catheterisation and mPAP computed from measurements on CMR



Mean Pulmonary artery pressure [mPAP] is expressed in mmHg.

Pearson's co-efficient of correlation = 0.916

Significance (p value) = 0.01

Other significant correlations between CMR parameters and mean pulmonary artery pressure (mPAP) measured on right heart catheterisation

CMR parameter	Pearson correlation	Significance (2-tailed)
Main pulmonary artery diameter	.908*	0.012
Pulmonary artery to aorta ratio	.895*	0.016
Diastolic eccentricity index	.910*	0.012
Interventricular septal angle	.912*	0.011

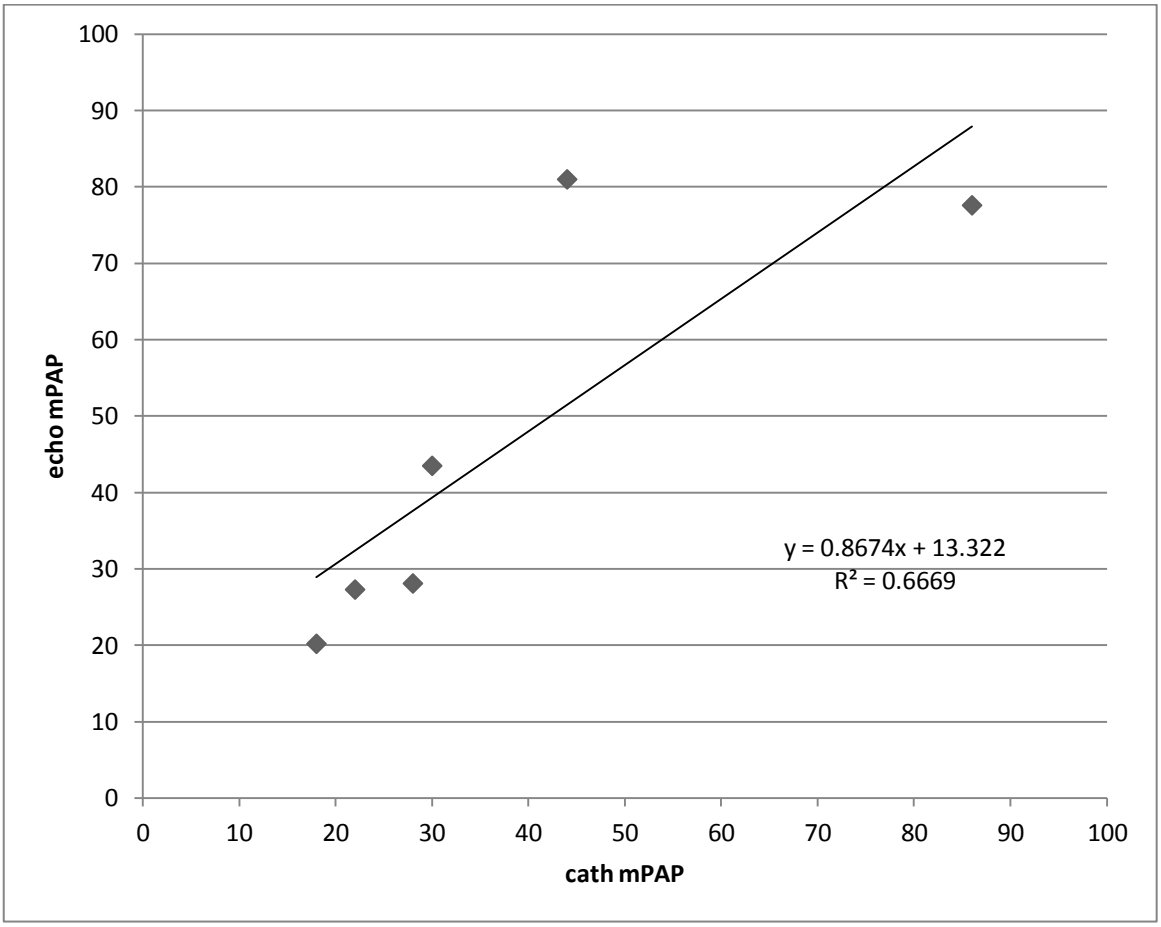
Although the number of subjects who underwent right heart catheterisation is small, these values show significant association suggesting a real linear association between the mentioned CMR parameters and severity of pulmonary hypertension.

Multivariate analysis of the statistically significant correlation CMR parameters with mean pulmonary artery pressure (mPAP)

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	35.374	66.558		.531	.603
	Pulmonary Artery to Aorta Ratio	34.292	25.164	.297	1.363	.194
	Ventricular mass index	70.058	92.540	.616	.757	.462
	Systolic eccentricity index	-16.676	31.477	-.206	-.530	.605
	Intervtricular septal angle	-.737	1.331	-.455	-.553	.589
	CMR derived mPAP	1.894	4.481	.539	.423	.679

Though the above parameters were individually significant, multivariate analysis was not significant.

Correlation between mean pulmonary artery pressure (mPAP) measured on right heart catherisation and that measured on Echocardiogram



Mean Pulmonary artery pressure [mPAP] is expressed in mmHg.

Sensitivity = 100%

Specificity = 50%

Positive predictive value = 80%

Negative predictive value = 100%

Discussion

A total of 366 cardiac magnetic resonance imaging [CMR] was performed during the study period from July 2014 to August 2015. A total of 29subjects either underwent CMR with a clinical suspicion of pulmonary hypertension or were suspected or diagnosed on CMR with the same. Of these, 7 subjects had one or more exclusion criteria such as congenital heart disease or significant myocardial infarction. Of the remaining 22subjects, 4 did not have Echocardiographic measurements for calculation of mean pulmonary artery pressure (mPAP). 18 patients had both CMR and Echocardiogram with values for calculating mean pulmonary artery pressure (mPAP).

Five subjects who were planned for right heart catheterisation were invited to participate in the study and undergo CMR. Two of these subjects refused consent. Of the three patients who consented to be subjects, right heart catheterisation was deferred for one patient. Hence 2 voluntary subjects entered the final analysis.

A total of 20subjects had both MRI and Echocardiogram and underwent statistical analysis for correlation. All were adults and there were more men than women. A total of 12subjects (60%) had Echocardiogram derived mean pulmonary artery pressure (mPAP) more than 25mmHg calculated by the standard formula specified in the methodology and the remaining had values less than 25mmHg.

Six of the subjects underwent right heart catheterisation and four of them had pulmonary hypertension which is 67%

Accuracy of CMR derived mean pulmonary artery pressure (mPAP)

The formula for derivation of mean pulmonary artery pressure on CMR is taken from a study by Swift et. al published in October 2013 called Non-invasive estimation of pulmonary artery pressure, flow and resistance using CMR (34). According to this formula all the studied subjects had a CMR derived mean pulmonary artery pressure (mPAP) of more than 25mmHg. This suggests a high sensitivity, however a low specificity. That is to say that this value overestimates the pulmonary pressure and balances with the Echo derived values at a cutoff value of around 34mmHg. However, this value compared with the mean pulmonary artery pressure derived showed a high degree of linear correlation with p value of 0.001.

The formula for derivation of mean pulmonary artery pressure on CMR uses two CMR parameters for its computation, viz., ventricular mass index [VMI] and interventricular septal angle. VMI shows a high degree of correlation with p value of less than 0.001, which is similar to other studies as detailed in the literature review. A recent systematic review suggests that the cut off value is 0.45 (35).

Interventricular septal angle also shows significant correlation, though less than VMI, with a p value of 0.008. Interventricular septal angle in systole is an indicator of septal bowing or bounce seen when there is pulmonary hypertension as the septum bulges more and more into the left ventricle with rising pressures causing the left ventricle to lose its circular nature on short axis and be deformed in systole becoming elongated parallel to the septum. This property is more accurately measured by the

eccentricity index in systole and shows a higher degree of correlation with mean pulmonary artery pressure (mPAP) with a p value of 0.005.

CMR derived mean pulmonary artery pressure (mPAP) compared with catheter derived mean pulmonary artery pressure (mPAP) also showed significant correlation with p value of 0.01 though the sample size for comparison was small. According to this formula all the studied subjects had a CMR derived mean pulmonary artery pressure (mPAP) of more than 25mmHg. This suggests a high sensitivity, however a low specificity. That is to say that this value overestimates the pulmonary pressure. However, owing to the small number of subjects studied, it is difficult to comment on the accuracy.

Correlation between CMR parameters and Echocardiogram derived mean pulmonary artery pressure (mPAP)

Highest correlation with a p value of less than 0.001 was seen for the following CMR parameters:

(1) Ratio of the diameter of the main pulmonary artery to that of the ascending aorta at the same level

(2) Ventricular mass Index

High degree of correlation, with a p value of less than or equal to 0.01 was seen for the following CMR parameters:

(1) Main pulmonary artery diameter on MRI

(2) Systolic eccentricity index

(3) Interventricular septal angle

Significant correlation with a p value of less than or equal to 0.05 was also seen for the following CMR parameters:

(1) Diastolic eccentricity index

(2) Normalised or indexed right ventricular mass in end diastole.

Main pulmonary artery diameter, though often measured by radiologists, is not considered important by the cardiologists and therefore significant correlation demonstrated on this study is favourable. However, this same measure, when expressed as a ratio over the diameter of the ascending aorta at the same level is of much more significance.

The other two main categories of parameters of significance are those related to the right ventricular mass and septal bowing.

Right ventricular mass in itself showed only moderately significant correlation with a p value of 0.058 which increased to p value of 0.049 when indexed. However, when this is expressed as a ratio over the left ventricular mass in diastole as ventricular mass index, it shows a high degree of correlation. Owing to this, the significance of right ventricular mass in the presence of significant left ventricular infarction is doubtful and may be misleading.

The other category of parameters of significance related to septal bowing or bounce includes the angle of the interventricular septum in systole and the eccentricity indices. In our study, systolic eccentricity index appears to be a marginally better indicator of septal bowing than the angle of the interventricular septum in systole, with loss in p value from 0.008 to 0.005. interestingly, the diastolic eccentricity index also shows a moderate significance of 0.028 suggesting right ventricular diastolic dysfunction. This function is also susceptible for error in the presence of significant regional or global wall motion abnormality in the presence of ischaemic heart disease.

Right ventricular volumes and function did not show significant correlation with mean pulmonary artery pressure (mPAP) measured on Echocardiogram in our study.

The left ventricular volumes function and masses also did not show significant correlation with mean pulmonary artery pressure (mPAP) measured on Echocardiogram in our study.

Correlation between CMR parameters and mean pulmonary artery pressure (mPAP) measured on right heart catheterisation

The sub-set of patients who underwent right heart catheterisation was small, being only 6. However, similar parameters such as ratio of main pulmonary artery diameter to ascending aorta, ventricular mass index and those related to septal bowing were found to be statistically significant.

High degree of correlation between mean pulmonary artery pressure (mPAP) measured on Echocardiogram and catheterisation was also observed in our study. Accuracy of diagnosis of pulmonary hypertension defined as mean pulmonary artery pressure (mPAP) more than 25 showed 100% sensitivity and negative predictive value. However specificity was only 50%.

Phase contrast imaging

In our study phase contrast analysis and values showed no statistically significant correlation with mean pulmonary artery pressure (mPAP). However the subset of patients who underwent phase contrast imaging is very small and therefore any statistical inference is deemed insignificant.

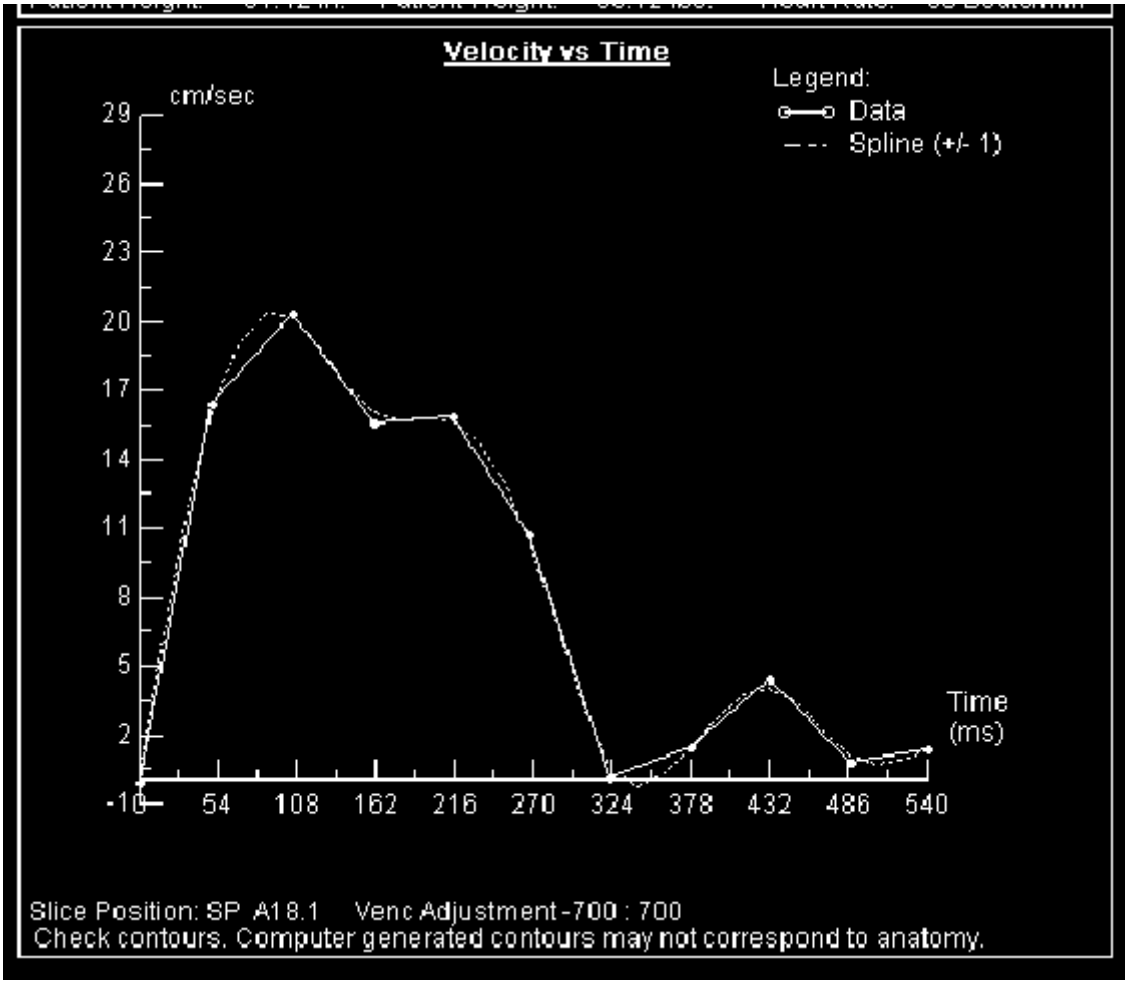


Figure 18

Graph showing velocity in cm/sec plotted against time in milliseconds in a patient with pulmonary hypertension due to mitral valve stenosis who underwent phase contrast imaging through the main pulmonary artery.

Qualitative assessment of CMR in those diagnosed with pulmonary hypertension based on Echocardiogram derived mean pulmonary artery pressure (mPAP) of more than 25mmHg.

1) On the axial images, the size of the main pulmonary artery appeared equal to or greater than that of the ascending aorta at the same level
2) Right ventricular hypertrophy was more apparent rendering the tracing of the endocardium and the epicardium of the right ventricle more easy and accurate
3) The papillary muscles and trabeculations of the right ventricle including the moderator band appeared larger and more prominent than in those with normal pressures.
4) Septal bounce was well appreciated on short axis CINE images in those with pulmonary hypertension, especially when played as a video.
5) Loss of circular contour of the left ventricle in systole was also well appreciated in short axis CINE images in those with pulmonary hypertension
6) The right ventricle appearing larger in end diastole was more often seen in those with pulmonary hypertension than in normal subjects, especially in relation to the left ventricle
7) In phase contrast imaging, patients with pulmonary hypertension appeared to have larger cross sectional area of the main pulmonary artery both in systole and diastole.
8) Those with higher pulmonary pressures appeared to have proportionately higher peak systolic velocity.

Limitations

1) The small sample size of the study is a major draw-back for this study. This is, however inevitable considering the time constrains and he rarity of the condition. Especially, the subset who underwent the Gold standard reference study is too small to infer any statistical analysis of significance.
2) Pulmonary pressures are known to very on a daily basis. But Echocardiography was performed several days prior to CMR or right heart catheterisation. This limits the direct comparison of the diagnostic accuracy of CMR versus Echocardiography for the detection of PH.
3) Echocardiography is a well-established screening tool in the evaluation of patients with suspected PH, and treatment is often started based on this. Implementation of CMR as a replacement for Echocardiography would be associated with several challenges, including cost, availability and expertise.
4) The right ventricular free wall is barely visible in the end diastolic images in normal subjects and therefore diastolic mass is liable to be over-estimated. This will reduce the statistical significance of right ventricular mass, thereby the ventricular mass index and consequently the CMR derived mean pulmonary artery pressure (mPAP).
5) Since all the subjects analysed had CMR derived mean pulmonary artery pressure (mPAP) higher than 25mmHg, this formula though showing a high degree of correlation with mean pulmonary artery pressure (mPAP) likely overestimates the pressures.

Conclusions

CMR is a versatile tool in the assessment of parameters that indicate right heart status and function which correlate well with measurement of mean pulmonary arterial pressures on Echocardiography and therefore may be used to diagnose and prognosticate pulmonary hypertension.

Ratio of the diameter of the main pulmonary artery to that of the ascending aorta at the same level and Ventricular mass Index showed the highest degree of correlation with mean pulmonary arterial pressures on Echocardiography and right heart catheterisation when available. Other significant parameters include those related to the motion of the interventricular septum in systole.

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Appendices

Data collection form

Identification number

Name of the patient

Hospital number

Gender of the patient

Age of the patient

Right heart catheterisation

Peak systolic pressure

Diastolic pressure

Mean pulmonary arterial pressure

Echocardiogram

Tricuspid regurgitant jet velocity

Pressure gradient across the tricuspid valve

Pulmonary artery systolic pressure

Mean pulmonary arterial pressure

CMR

Main pulmonary artery diameter on MRI

Pulmonary artery to aorta ratio

Right ventricular ejection fraction

Right ventricular end diastolic volume

Right ventricular end systolic volume

Right ventricular stroke volume

Right ventricular mass in end diastole

Right ventricular end diastolic volume index

Right ventricular end systolic volume index

Right ventricular stroke volume index

Right ventricular mass index

Left venricular ejection fraction

Left ventricular end diastolic volume

Left ventricular end systolic volume

Left ventricular stroke volume

Left ventricular mass in end diastole

Left ventricular end diastolic volume index

Left ventricular end systolic volume index

Left ventricular stroke volume index

Left ventricular mass index

Ventricular mass index

Intervtricular septal angle

Systolic eccentricity index

Diastolic eccentricity index

Phase contrast imaging

Phase contrast peak velocity

Phase contrast average velocity

Phase contrast forward volume

Phase contrast reverse volume

Percentage retrograde flow

Phase contrast net forward volume

Phase contrast net forward volume indexed

Pulmonary artery systolic area

Pulmonay artery diastolic area

Pulmonary area distensibility

Phase contrast pulmonary artery relative area change

CMR derived mpap

Tamil Patient information sheet and consent form

ஆய்வில் பங்கேற்பதற்கான தகவலறிந்த ஒப்புதல் வடிவம்

ஆய்வின் பெயர்: ***எம். ஆர். ஐ. ஸ்கான் மூலம் நுரை ஈரலில் உள்ள இரத்தக் குழோய்களில் ஏற்படும் இரத்த கொதிப்பை கண்டரித்தல்***

இந்த தாழ் நீங்கள் பங்கு பெற அழைக்கப்படும் ஆய்வை குறித்த தகவல்களை கொண்டது. இதை கவனமாக வாசிக்கவும். உங்கள் சந்தேகங்களை கேட்டு தெரிந்து கொள்ளலாம். இந்த ஆய்வில் உங்கள் பங்கேற்பு முத்திரிலும் உங்கள் விருப்பத்தை பொருத்தது.

ஆய்வின் நோக்கம்

எம். ஆர். ஐ. பரிசோதனை இருதயத்தின் வலது புறத்தை துல்லியமாக படம் பிடிக்க கூடியது. இதன் மூலம் உங்கள் நுரை ஈரலில் உள்ள ரத்த குழாய்களின் செயல்பாட்டை அறியலாம். இந்த விளைவுகள் உங்கள் மருத்துவருக்கு தெரிவிக்கப்பட்டு, உங்கள் சிகிச்சை மேம்பட வழிவகுக்கும். இந்த ஆய்வின் விளைவுகள் உங்களைப்போன்ற மற்ற நோயாளிகளும் சிறந்த சிகிச்சை பெற உதவும்.

இருதய எம். ஆர். ஐ. என்றால் என்ன?

இது ஒரு விதமான படம் பிடிக்கும் கருவி. இதில் எக்ஸ்-ரே ஏதும் கிடயாது. நீங்கள் ஓர் மேஜையில் படுத்து, வட்டமான ஓர் கருவிக்குள் அனுப்பப்படுவீர்கள். இதன் பொழுது அநேக விதமான சத்தங்கள் காேட்க கூடும். காந்தக கதிர்கள் மூலம் உங்கள் இருதயம் படம்பிடிக்கப்படும். இந்த படங்களை பார்த்து உங்கள் மருத்துவர் உங்கள் வியாதியை பற்றி அறிந்துகொள்வார். இதற்கு 10-15 நிமிடங்கள் ஆகலாம். ஸ்கான் பொழுது நீங்கள் அசையாமல் படுத்திருப்பது அவசியம்.

இதில் உண்டான ஆபத்துகள் யாவை?

இந்த ஸ்கான் மூலம் எந்த ஆபத்தும் இல்லை.

இதற்கு ஏதாவது பக்க விளைவுகள் உள்ளனவா?

இல்லை

உங்கள் விவரங்கள் பாதுகாக்கப்படுமா?

இந்த ஆராய்ச்சி மருத்துவ இதழ்களில் வெளிவரும். ஆனால் உங்கள் பெயரோ, சொந்த விவரங்களோ யாரிடமும் அறிவிக்கபடாது.

உங்களைப்பற்றிய தகவல்கள் அனைத்தும் ஆய்வாளர்களுக்கு மட்டும் தெரிந்திருக்கும். வேறு யாரிடமும் தெரிவிக்கப்படமாட்டாது.

ஆய்விலிருந்து விலகுவது

நீங்கள் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து விலகிக்கொள்ளலாம். அதனால். உங்கள் சிகிச்சை பாதிக்கப்படாது.

கூடுதல் செலவு

இந்த எம். ஆர். ஐ. ஸ்கான் உங்களுக்கு முத்திரிலும் இலவசமானது. இதற்கு நீங்கள் எந்த செலவும் செய்ய வேண்டியதில்லை.

ஆராய்ச்சியின் முடிவென்ன?

இது உங்கள் வ்யாதியியை கண்டறியவும், தொடர்ந்து கண்காணிக்கவும் உதவகூடும்.

இதனால் மற்றவர்களும் பயனைடைவார்கள்.

உங்களுக்கு மேலும் கேள்விகளிருந்தால் தொடர்புகொள்ள வேண்டிய தொலைபேசி எண்: *Dr.* பவுல் தீபக், *9551555313*

ஒப்புதல் வடிவம்

ஆய்வின் பெயர்: ***எம். ஆர். ஐ. ஸ்கான் மூலம் நுரை ஈரலில் உள்ள இரத்தக் குழோய்களில் ஏற்படும் இரத்த கொதிப்பை கண்டரித்தல்***

_____ அவர்களின் மகன் / மகள் -ஆகிய

நான் _____

1. *இந்த ஆய்வு குறித்து எனக்கு வழங்கப்பட்ட தகவல் தாளை படித்து என் சந்தேகங்களையும் தெளிவுபடுத்தினேன் என்று அறிவிக்கிறேன். [ ]*

(தயவு செய்து பெட்டிகளை குறிக்கவும்)

2. *இந்த ஆய்வில் என் பங்கு முற்றிலும் தன்னார்வமானது. மேலும் என் வழக்கமான சிகிச்சை அல்லது என் சட்ட உரிமைகளை பாதிக்கும் எந்த நேரத்திலும் பங்கேற்பை நிறுத்த எனக்கு அனுமதி உண்டு என்று புரிந்துக்கொண்டேன். [ ]*
3. *நான் ஆய்விலிருந்து விலகினாலும். ஆய்வாளர்கள் என் சிகிச்சை விவரங்களை பரிசீலிக்க உரிமை உண்டென்று அறிகிறேன். [ ]*
4. *மருத்துவ ஆராய்ச்சிக்காக உதவக்கூடும் என்னுடைய எந்த தகவலையும் பயன்படுத்த நான் தடைகூர மாட்டேன். [ ]*
5. *இன்னை பற்றிய சொந்த தகவல்களையோ, அடையாளத்தையோ யாகுக்கும் தெரியப்படித்துவதில்லை அன்று அறிகிரியன். [ ]*
6. *என் சொந்த வ்ருப்பத்தினால் இந்த ஆராய்ச்சியில் பங்கேற்கிறேன். [ ]*

ஆய்வில் பங்குபெறுபவரின் கையொப்பம்(அல்லது கை நாட்டை):

தேதி: _____ / _____ / _____

பெயர்: _____

கையொப்பம்:

ஆய்வு ஆரோய்ச்சியாளரின் கையொப்பம்: _____

தேதி: _____ / _____ / _____

ஆய்வு ஆரோய்ச்சியாளரின் பெயர்: _____

சாட்சியின் கையொப்பம்: _____

தேதி: _____ / _____ / _____

சாட்சியின் பெயர் & முகவரி: _____

English patient information sheet and consent form

Patient information sheet

Study title: Role of Cardiac MRI in Pulmonary Hypertension

The following information is provided to inform you about this study and your participation in it. Please read the information carefully and you are free to ask questions regarding the study and the information given. Participation in this study is purely voluntary and you are free to withdraw from the study anytime.

Purpose of the study

Cardiac MRI is a non-invasive test which is useful for taking various measurements of the heart and making various calculations in pulmonary hypertension. The results of this scan will help your doctor to know more about your disease condition and treat you better. The results of this study will also help to treat other patients with similar illnesses better.

What is cardiac MRI?

Cardiac MRI is a non-invasive test which is useful for taking various measurements of the heart and making various calculations in pulmonary hypertension. The MRI machine is a tube with a central opening that is about three feet wide. The patient lies on the table and the table slides into the central opening. Pictures of the heart are created using a magnetic field, radio waves and computers. X-Rays are not used in this scan at all. These images will allow the doctor to know more about the structure and function of your heart and treat you better.

What are the risks involved in undergoing this test?

There are no specific risks particular for this kind of scanning.

Confidentiality

Your participation in this study will remain confidential and shall be known only to the investigators. The results of the study will be published in medical journals, but your personal identity such as name and address will not be disclosed to anyone.

Withdrawal from the study

Participation in this study is purely voluntary and you can withdraw from the study anytime without explaining any reasons. It will not compromise your treatment in any way.

Additional costs

Cardiac MRI is done free of charge for you. You will not need to pay any extra charges.

Detailed information about the procedure

Before the test

You have to give your consent in writing prior to the test.

There are no specific prior preparations or precautions for this test.

The day of the test

The actual test takes only about 10 to 15 minutes. However, make arrangements to stay for 2-3hours from the time you arrive to the time you leave. Please arrive at MRI room 3 one hour prior to the scheduled test time. You will be asked to change into a hospital gown and remove all jewellery, dentures and hearing aids.

During the test

The test takes only about 10 to 15 minutes. You will be asked to lie down on a table that goes into the MRI scanner and connected to a machine that monitors your heart beat. Once the test starts, you will hear various sounds as the machine takes pictures. We will also prompt you with instructions. For example, we may ask you to hold your breath for 8 to 10 seconds at a time. It is important that you stay as still as possible because movements can create glitches in the pictures.

After the test

You may resume your normal activity immediately after the test.

The test results will be sent to the doctor who is treating you in OPD by the following day. You will need to contact your treating doctor to discuss the results of your test. Keep any scheduled follow-up appointments with your primary doctor.

For any querries, kindly contact Dr. Paul Deepak S., PG Registrar, department of Radiology, CMC, Vellore.

Mobile - 9551555313

Informed Consent Form for Subjects

Study Title: Role of cardiac MRI in Pulmonary Hypertension

Study Number: _____

Subject's Initials: _____

Subject's Name: _____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

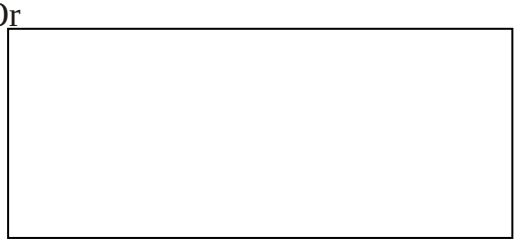
(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or



Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name:Dr. Paul Deepak S, PG Registrar in Radiodiology, CMC, Vellore

Signature (or) thumb impression of the Witness: _____

Date: _____/_____/_____

Name and Address of the Witness: _____

Hindi patient information sheet and consent form

रोगी जानकारी पत्र

अध्यन का नाम: पुल्मनरी हाइपरटेन्षन की जाांच मे हृदय के एम.आर.ऐ. की भूममका यहे जानकारी पत्र आपको इस अध्यन की तथा ऊसमे आपकी भूममका के विषय मे जानकारी देगा। कृपया इस जानकारी पत्र को ध्यान से पढ़िये। ईस अध्यन के विषय मे आपको जो कोई प्रश्न होइगे ि◌ो आप पूछ सकते है। ईस अध्यन मे भागीदारी पूरी तरहसे स्ि◌ैचचख है, और आप कामभमभ इस अध्यन से आपका नाम ि◌ापस ले सकते है।

इस अध्यन का उद्देश्
हृदय का एम.आर.ऐ एक सुलभ जाांच है जजश मे पेशेंट को कोई तकलीफ के मभना हृदयके और पुल्मनरी हाइपरटेन्षन के बारेमे जानकारी प्राप्त होती है। ईस टेस्ट से जो जानकारी प्राप्त होगी ि◌ो आपके इलाज मे आपके डॉक्टर को मदत करेगी।

हृदय का एम.आर.ऐ क्या है?
यह अक नई तकनीक है जीससे हृदय के बारेमे जानकारी प्राप्त होती है। ईस जाांच मे हाननकारक रेडीयेशन ककरणोका प्रयोग नहीांं होता। इस तकननत मे पेशेंट को अक बेडे चुम्बक मे लटना पडता है जजसकी मदतसे हृदय के बारेमे जानकारी प्राप्त होती है।

क्या इससे ककसी प्रकार का खतरा है?
इससे मरीजो को ककसी भी प्रकार का खतरा नहीांं है।

क्या मुझे इस जाच के लीये पयसे देने होंगे?
मरीजो को इस जाच केलीये कोई पैसा नहीांं देना होगा।

क्या आपका व्यागततगत वि◌िरण गोपनीया रखा जायेगा?
इस अध्यन से ममले पररणाम को ककसी भी जननल मे प्रकामशत ककया जायेगा, पर आपका नाम ककसी भी जगह पर नहीांं मलया जायेगा। परांतु, आपके चचककत्साल्य के ररकॉडन की समीक्षा हो सकते है उन लोगो के दिारा जो इस अध्यन से जुडे है, और ये आपकी जानकारी के बेगार हो सख्ता है।

क्या आप इस अध्यन से अपना नाम ि◌ापस ले सकते है?
इस अध्यन स्◌ैचक है, आप इस अध्यन से अपना नाम कभी भी ि◌ापस ले सकते है। इस से आपका कोई भी नुकसान नही◌ां होगा।

अध्यन के बारमे जानकारी

टेस्ट के पेहेले:
- आपको सहमती पत्र पर हस्ताक्षर करने होगे
- एस टेस्ट के मलया होई विशेष टयारी की जरूरत नही◌ां है

टेस्ट के ददन:
- इस टेस्ट को पूरा होने के मलये १० से १५ मीनेटोका ि◌क्त लगता है
- कृपया टेस्ट के समय से एक घांटा पढहले आप एम आर ई रोम ३ मे पहुचे
- आप को अस्पताल के कपडे पहनने अडांगे
- सभी पहनी होई चीजोंको आपको ननकालना पडेगा

टेस्ट के दोरान:
- आपको एम आर ई तबले पर लटना होगा। इसके बाद आपके हृदय धडकनोका रेकॉर्डिंग ककया जायेगा। एम आर ई स्कॅन चालू होनेपे आपको अलग अलग तरह के आिाज सुनाई दांगे।
- आपको अलग अलग सूचनाए ढदया जाएंगी, जैसे की आप को ८ से १० सेकोंडकों के मलये सा◌ांस बांद करनेको कहा जायेगा
- इस टेस्ट के दौरान आपको बबल्कुल ढहलना नही◌ां है

टेस्ट के बाद:
- एस टेस्ट के बाद आप तुरांत आपका रोजका काम चालू कर सकते है
- यहे टेस्ट के ररपोटन आपके डॉक्टर के पास भेजे जायांगे।
- आप आपके डॉक्टर से ममलके इस टेस्ट के ररज़ल्ट के बारे मे जानकारी प्राप्त कर सकते है

ककसी भी प्रकार की अचधक जानकारी के लेये कृपया सांपकन करे डाक्टर पॉल दीपक **(955155313)** या **email:**pauldchristian@gmail.com

अध्यन का नाम: पुल्मनरी हाइपरटेन्षन की जाांच मे हृदय के एम.आर.ऐ. की भूममका

अध्ययन संख्या:

प्रततभागी का नाम:

जन्म / Age की तारीख (व्ोां में):

हचपताल नंबर:

मे_____ बेर्ा / बेर्ी _____

एलान करता हूकी मैने जानकारी पत्र को पढा है / इस जानकारी पत्र को मेरे ललये पढा गया है,

तथा मेरे सन्देहोंका चपचर्ीकरण क्रकया गया है

मैंयह भी समजता हूँक्रक इस अध्ययन मेंमेरी भागीदारी परूी तरह चवैस्च्छक हैऔर मझु ेमेरेसामान्य उपिार

और अपनेकाननू ी अधधकारों का ज्ञान है. मेंजनताा हूकी एस अनमतत ु को वापस लेनेके ललए मेंचवतंत्र

हुऔर इससे मेरे इलाज पर कोई असर नहीं होगा

मैंसमझता हूँक्रक अध्ययन कमटिाररयों और संचथागत नैततकता सलमतत के सदचयों को मेरे उपिार ररकॉिट

को देखने के ललये मेरी अनमु तत की जरूरत नहीं हैऔर उसका ऊपयोग करने के ललय सहमती देता हू

मैंसमजता हूकी इस अध्यन के पररनाऊ पर मेरा होई अधधकार नहीं होगा

मैंसमझता हूँक्रक मेरी पहिान क्रकसी तीसरेपक्ष को जारी या प्रकालित जानकारी मेंखुलासा नहींक्रकया जाएगा

मैंचवेछिा इस अध्ययन मेंभाग लेनेके ललए सहमती देता हू

नाम:

हचताक्षर / अगं ठूेका तनिान

ततधथ:

गवाह का नाम:

भागीदार के संबंध:

ततधथ:

अन्वे्क का हचताक्षर:

ततधथ:

Telugu patient information sheet and consent form

రోగి సమాచారం షీట్ :

స్టడీ పేరు: ఊపిరితిత్తుల రక్తపోటు లో కార్డియాక్ MRI పాత్ర.

క్రింది సమాచారం ఈ స్టడీ లో మీ పాత్ర గురించి మీకు తెలియజేయడానికి అందించబడుతుంది. జాగ్రత్తగా సమాచారం చదివీణతరువాత ఏమయెన ప్రశ్నలు ఉంటే స్వేచ్ఛగా అడగండి. ఈ స్టడీ పాల్గొనడం పూర్తిగా మీ స్వచితం, మీరు ఎసమయములోన్యెన వదని చ్చెపచ్చూ.

ఈ స్టడీ ఎందుకు చెస్తునాము:

కార్డియాక్ MRI గుండె మరియు ఊపిరితిత్తుల రక్తపోటు తెలుచుకూడానికి మరియు వీటిగురించి వివిధ లెక్కలను చేయడానికి ఉపయోగకరంగా ఉంతుంది. ఈ స్కాన్ ఫలితాలు మీ వ్యాధి పరిస్థితి గురించి మరింత తెలుస్తుంది. మీకు మరియు ఇలాంటి వ్యాధులతో ఉన్న ఇతరులకు మంచి చికిత్స చేయడానికి సహాయపడుతుంది.

గుండె MRI అనగా ఏమిటి?

కార్డియాక్ MRI గుండె మరియు ఊపిరితిత్తుల రక్తపోటు తెలుచుకూడానికి మరియు వీటిగురించి వివిధ లెక్కలను చేయడానికి ఉపయోగకరంగా ఉంతుంది. MRI యంత్రం గుండ్రంగా ఉంతుంది. దానీలో మీరు కదలకుండా పాడుకోవాలి. దానిద్వార గుండె యొక్క చిత్రాలు వస్తాయి. అపుడు మీ గుండె గురించి మరింత తెలుసుకునిందుకు మరియు మీరు మంచి చికిత్స చేయడానికి అనుమతిస్తుంది.

ఈ పరీక్ష వలన ప్రమాదాలు ఏమిటి?

ఈ పరీక్ష వలన మాకు తెలిసినంతవరకు ఏమి ప్రమాదాలు లేవు.

గోప్యత:

ఈ స్టడీలో మీరు పాల్గొనడం రహస్యంగా ఉంతుంది, పరిశోధకులు మాత్రమే తెలుస్తుంది

స్టడీ నుండి ఉపసంహరణ:

ఈ స్టడీ పాల్గొనడం పూర్తిగా స్వచితం మీరు ఎప్పుడైనా ఏ కారణాలు వివరిరించకుండా స్టడీ నుండి వెనక్కి తీసుకోవచ్చు. ఇది ఏ విధంగా మీ చికిత్సకు రాజీగా ఉండదు.

విధానం గురించి సమాచారం:

పరీక్ష ముందు మీరు పరీక్ష చేయిన్చుకున్టామని రచన లో మీ అనుమతి ఇవ్వాలని. ఈ పరీక్ష కోసం ప్రత్యేకమైన ముందు తయారి లేదా ముందు జాగ్రత్తలు లేవు.

పరీక్ష రోజు ఏమేచేయాలి:

పరీక్ష రోజు మీకు ఇచిన సమయానికికంటే ఒక గంట ముందు MRI రూమ్ను నెంబర్ది 3 కు రంది. వద్దకు దయచేసిఅసలు పరీక్ష మాత్రమే 15 10 నిమిషాలు పడుతుంది. మీరు ఒక ఆసుపత్రి గౌను లోకి మారుచుకొని, అన్ని ఆభరణాలు, దంతాలు మరియు వినికిడి పరికరాలు తిసయాలి. అసలు పరీక్ష 15 10 నిమిషాలు మాత్రమే పడుతుంది. దానితరువాత 2 గంటలు మీరు ఉండవలసివస్తుంది.

పరీక్ష సమయంలో ఏమిచేయాలి:

పరీక్ష 15 10 నిమిషాలు మాత్రమే పడుతుంది. మీరు MRI స్కానర్ లోపల కదలకుండా పాడుకోవాలి. మీ గుండె కొట్టుకోవడం పర్యవేక్షించే ఒక యంత్రం కనెక్ట్ చేస్తారు. పరీక్ష ప్రారంభమఎనతరువత మీరు వివిధ ధ్వనులను వేనిపెస్థాయి. దానిద్వర మీరు బయపదవదు. మేము కొని ఆదేశాలకు చెపుతాము. ఉదాహరణకు, మేము ఒక సమయంలో 8-10 సెకన్లు మీ శ్వాసను భిగిచమని అడగవచ్చు.

పరీక్ష తర్వాత:

మీరు పరీక్ష తర్వాత వెంటనే మీ సాధారణ కార్యకలాపాలు చేయవచు. పరీక్ష ఫలితాలు మరుసటి రోజు OPD లో మీకు చికిత్స చేసే డాక్టర్కికి పంపబడుతుంది. పరీక్ష తరువాత చికిత్స చేసే డాక్టర్ని సంప్రదించాలి.

ఏ మయిన అడుగాలంటే, దయచేసి డాక్టర్ పాల్ దీపక్ ఎస్, పీజి రిజిస్ట్రార్, రేడియాలజీ, CMC వెల్లూర్య ని అడుగండి. మొబైల్ – 9551555313.

పార్టిసిపెంట్ యొక్క పేరు:

పుట్టిన / వయసు తేదీ (సంవత్సరాలలో):

I_____, కొడుకు / కూతురు

_____

నేను చదివాను / ఈ అధ్యయనం గురించి నాకు అందించిన సమాచారం షీట్ చదివి చేయబడింది మరియు నేను కలిగి ఉన్న అనుమానాలను వివరించారు చేసిన ప్రకటిస్తాయి. [ ]

(దయచేసి **టిక్ పెటండి**)

నేను కూడా ఈ అధ్యయనంలో నా పాల్గొనడం పూర్తిగా స్వచ్ఛంద మరియు నా సాధారణ చికిత్స లేదా నా చట్టపరమైన కు ప్రభావితం లేకుండా ఏ సమయంలోనైనా పాల్గొనేందుకు కొనసాగించడానికి అనుమతి ఉపసంహరించుకోవాలని ఉచిత అని అర్థం [ ]

నేను విచారణ నుండి వెనక్కి కూడా అధ్యయనం సిబ్బంది మరియు ఎథిక్స్ కమిటీ సభ్యులు సంస్థాగత నా ఆరోగ్య రికార్డులను కు నా అనుమతి అవసరం లేదు అని అర్థం. నేను ఈ యాక్సెస్ అంగీకరిస్తున్నారు [ ]

అటువంటి ఒక ఉపయోగం అందించిన ఈ అధ్యయనం ద్వారా ఉత్పన్నమయ్యే ఏ డేటా లేదా ఫలితాల ఉపయోగం పరిమితం అంగీకరిస్తున్నారు మాత్రమే శాస్త్రీయ ప్రయోజనం [ ]

మీ గుర్తింపును మూడవ పార్టీలు విడుదల లేదా ప్రచురించబడిన ఏ సమాచారాన్ని బహిర్గతం చెయ్యబడదు అర్థం.

నేను స్వచ్ఛందంగా ఈ అధ్యయనంలో పాల్గొనేందుకు మీరు అంగీకరిస్తున్నారు[ ]

పేరు:

సంతకం:

తేదీ:

సాక్షి పేరు:

అభ్యర్థి సంబంధం:

తేదీ: